Comments on General Rules
Rose Baran Pharm.D.

Rule 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.
(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of ~~inpatients~~ **patients of a medical institution** shall be supervised by a pharmacist ~~who is on the premises~~ of the medical institution.
Removing "who is on the premises" does not allow the technicians to remain in the pharmacy working while the pharmacist is at meeting in the hospital or on the floor or etc. This negates the original intent to allow the pharmacist to be in the hospital but not in the pharmacy and let the technicians remain to continue drug preparation for the pharmacist review. This allows the pharmacist of small hospitals to attend meetings and other issues outside of the pharmacy but on the hospital premises. This would enable small hospitals to stay open and serve the public health of the community.

Rule 338.503 **Prescription drugs and devices; return or exchange for resale prohibited.**
Add to this rule the return of drugs for a manufacturer recall that is down to the patient level or when the wrong medication was dispensed to the patient. This then would align with 21 CFR part 1317.
Add suggested language: (d) The provisions of subsection (1) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock.
This would encourage the removal of harmful drugs.

Rule **338.513 Educational limited license; application and renewal; practices.**
Need to add to the rule the human trafficking requirement.
Add suggested language: (6) Applicants need to complete the training in human trafficking for licenses issued after November 13, 2022 as required in Rule 338.511.

Rule 338.519 **Examinations adoption; passing scores; reexamination.**
(4) If an applicant for licensure fails to pass either of these examinations, he or she shall provide the board, after each failed attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.

This section needs to be dropped as even the National Association of Boards of Pharmacy (NABP) allow for 5 attempts before any remediation is needed. This would be very costly and increase the pressure on passing this exam. No other health profession has this strict requirement. Also, none of the Great Lakes States have this strict requirement. One allows 2 failures, 2 allow 3 failures and the others follow the NABP. Suggest adding back language that would allow 5 attempts, suggested language: (4) An applicant who has not received a passing score on the NAPLEX and or MPJE examinations after 5 attempts shall provide certification from an approved education program certifying that he or she satisfactorily completed courses

that provide a thorough review of the area or areas that he or she failed in the most recent examination.
To be able to mandate this NABP has to provide to the applicant the areas they failed in, which I believe is not done currently.

(7) An applicant shall not sit for either exam specified in subrule (5) or (6) of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), or successfully repeats the foreign pharmacy graduate equivalency examination committee certification program administered by the NABP, and provides proof of completion to the board.
This section (7) as currently written would require the applicant to completely redo the pharmacy degree and not just the sections they failed. Yet a foreign graduate would not have to do so.

R 338.531 Pharmacy license; applications; requirements.
(3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared or dispensed, each address location shall obtain a separate license.
This should be changed to read: (3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared, or dispensed, or prescriptions received, each address location shall obtain a separate license.
This is to align with MCL 333.17722 and also require any location where prescriptions are dropped off for filling would need to be licensed.

(4) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. This includes, but is not limited to, USP Chapters 795 and 800.
Add USP Chapter 797 to this to make it consistent with Rule 338.533(1).

R 338.533 Sterile compounding standards and requirements; outsourcing facilities; requirements.
(7)(d) Label compounded drugs with all of the following:
(i) Required drug and ingredient information.
(ii) Facility identification.
(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."

Change this to:
"(d) label compounded drugs in compliance with the Federal Food, Drug, and Cosmetic Act 503B(10) and rule 338.582."
The label must include the requirements of both the state and federal law.

This would be easier to quote the federal law at **(7)(d)** instead of listing all of the following.
"``(10) Labeling of drugs.--
``(A) Label.--The label of the drug includes--

``(i) the statement `This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

``(ii) the name, address, and phone number of the applicable outsourcing facility; and

``(iii) with respect to the drug--

``(I) the lot or batch number;

``(II) the established name of the drug;

``(III) the dosage form and strength;

``(IV) the statement of quantity or volume, as appropriate;

``(V) the date that the drug was compounded;

``(VI) the expiration date;

``(VII) storage and handling instructions;

``(VIII) the National Drug Code number, if available;

``(IX) the statement `Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement `Office Use Only'; and

``(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient."

Also, the label needs to meet the requirements in Rule 338.582, and it would be easier to state the rule number and not all the details in the rule.

R 338.536 Housing of a pharmacy.
(2) All pharmacies shall have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that includes a prescription counter that provides not less than 10 square feet of free working surface.

The 150 square feet requirement has been in the rule for over 30 years. Given the increase in technology and the number of drugs requiring an increase in space this minimum should be at least 250 square feet for any new licenses issued. 250 square feet is used by a couple of the great lake states.

(3).....A pharmacy department must be locked when the pharmacist is not on the premises.

Add exception here for restroom breaks and assisting patients in the over the counter purchases.

R 338.538 Closing a pharmacy.

Rule 38. (1) A pharmacy that is ceasing operations shall return to the department the pharmacy license and the controlled substance license, if applicable, and shall provide the department with written notification of all of the following at least 15 days prior to closing:
Change this to 14 days to coincide with federal requirements.

R 338.561 Pharmacy as wholesale distributor; licensure.
Rule 61. (1) A pharmacy that transfers prescription drugs or devices shall obtain a wholesale distributor license if it satisfies either of the following:
(b) Prepares or compounds prescription drugs for resale, compounding or dispensing by another person in an amount that exceeds 5% of the total number of dosage units prepared and compounded for dispensing by the pharmacy during a consecutive 12-month period.

Need to drop (b) entirely as (b) is in violation of 333.17748a(7) and the Drug Quality and Security Act section 503A, a pharmacy may only compound a drug for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner. A pharmacy may not compound drugs for resale.

R 338.582 Prescription drug labeling and dispensing.
(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This subrule does not apply if the prescriber indicates "do not label."
Need to drop "**or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products**" from the rule. The rule was created before computer software was standard practice in pharmacy over 30 years ago. This terminology is no longer used on prescription labels because computers made it obsolete.

R 338.584 Noncontrolled prescriptions.
(4) A prescription is valid for 1 year from the date the prescription was issued.
Change this to read: (4) A noncontrolled prescription is valid for 1 year from the date the prescription was issued.
This makes it clear this only applies to noncontrolled prescriptions.

R 338.585 Customized patient medication package.
(b) A CPMP must be accompanied by a patient package insert. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

Change this first sentence to: "A CPMP must be accompanied by any mandated patient information required under federal law."
This would cover any medication guides required.

R 338.587 Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.
Rule 87. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.
(2) A pharmacy may utilize a manual system of recording refills if the system is in compliance with both of the following criteria:
(a) The amount and date dispensed must be entered on the prescription in an orderly fashion and the dispensing pharmacist initials the entry. If the pharmacist only initials and dates the prescription, then the full face amount of the prescription must be deemed dispensed.
(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.
Delete (2) entirely as this method is outdated by the use of computers. This part is more than 40 years old with no one using this process today.

R 338.588 Automated devices.
(3) A pharmacy that operates an automated device under this section shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.

Add to this: **(3) A pharmacy that operates an automated device under this section shall notify the department of the automated device's location on a form provided by the department.** *If the automated device contains controlled substances, the pharmacy must obtain an additional controlled substance license for the automated device as well as a DEA registration for the device.* **An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.**

(5) An automated device that is to be used for furnishing medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109(4), must be supplied and controlled by a pharmacy that is licensed in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error-prevention technology that complies with R 338.3154. Each automated device must comply with all of the following provisions:
Rule 338.3154 does not identify what is "board-approved error-prevention technology" and refers back to rule 338.490 which is being rescinded by the new draft rules. 338.3154 and 338.490 go around in a circle without ever defining "board-approved error-prevention

technology". Will have to define "board-approved error-prevention technology" and list those that have been board approved.

R 338.589 Professional responsibility; "caregiver" defined.
(5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code, MCL 333.16215, and under the personal charge of the delegating pharmacist, except as provided in R 338.486(3).
There is no longer an exception in R 338.486(3).

MHA
Michigan Health &
Hospital Association

Leading Healthcare

Sept. 19, 2019

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Boards and Committees Section
Board of Pharmacy - General Rules
ORR #2018-039 LR

Attention: Policy Analyst
P.O. Box 30670
Lansing, MI 48909
BPL-BoardSupport@michigan.gov

Dear Policy Analyst:

On behalf of the Michigan Health & Hospital Association (MHA), we respectfully submit the following comments on the Board of Pharmacy - General Rules.

Under the "Inspections of applicants and licensees" section, the MHA feels the inspection should also exclude data gathered by the licensed health facility for quality improvement or professional practice review purposes. The collection of quality improvement data enables providers to work to improve patient safety and reduce the incidence of adverse events. This data could be incorrectly interpreted, which may deter providers from collecting data for quality improvement purposes. Professional practice evaluation is the process by which a health facility, using its own medical staff, performs a peer review of a privileged practitioner's professional practice for performance improvement and to ensure safe and high-quality patient care. The data should to be left out of the inspection to ensure honest research and responses, which will ultimately lead to improved patient safety and quality. Michigan hospitals are committed to transparency and share quality of care data to state residents at verifymicare.org.

In the section for "Internship requirements," we trust the Board will carefully review and consider who it will allow to verify hours. We understand allowing more than a licensed pharmacy preceptor or approved education program for future flexibility but currently, the MHA does not see a category of "others" who are qualified to do this.

Under the "Practice of Pharmacy" Section, the new North American Pharmacist Licensure Examination (NAPLEX) and Michigan Multistate Pharmacy Jurisprudence Examination (MPJE) passing requirements raised some apprehension among hospital membership. While we respect the proposal to safeguard competent pharmacists to enter the workforce, the MHA wants to ensure qualified candidates are not inadvertently vetted out. Other variables, including education, prior employment, internships, residencies and skills which are valuable to hospitals are not defined by exams alone. Additionally, one day of poor-performance during a test can happen, and students deserve another try before they are required to provide satisfactorily completed courses information to the Board.

Brian Peters, *Chief Executive Officer*
MHA Capitol Advocacy Center | 110 W. Michigan Avenue, Suite 1200 | Lansing, MI 48933 | (517) 703-8601 | www.mha.org

Under the "Pharmacist licensure by examination" section, it is important to note that Canadian Council for Accreditation of Pharmacy Programs uses different criteria than the Accreditation Council for Pharmacy Education.

Lastly, a few technical changes such as updating proper names, adjusting words to align with the Public Health Code and incorporating other already Board-approved sterile compounding inspection organizations have been included in the comments.

The attached document includes the suggested language directly updated on the draft rules. Thank you for your consideration of our comments. Please reach out to Paige Fults (pfults@mha.org) with questions.

Respectfully submitted,

Adam Carlson
Senior Director, Government & Political Affairs
Michigan Health & Hospital Association
Desk: (517) 886-8245 | Cell: (269) 757-2479
acarlson@mha.org

LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

Filed with the Secretary of State on

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

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145, 16148, **16174, 16175, 16178, 16182, 16186, 17722, 17731, 17737, 17746, 17748, 17748a, 17748b, 17751, 17753, 17757, 17760,** and ~~17721~~ 17767 of 1978 PA 368, MCL 333.16145, 333.16148, **333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.17722, 333.17731, 333.17737, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17751, 333.17753, 333.17757, 333.17760,** and ~~333.17721~~ **333.17767**, and Executive Order Nos. 1991-9, 1996-2, ~~2003-01~~ **2003-1**, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and MCL 445.2030)

R 338.486 of the Michigan Administrative Code is amended; and R 338.471, R 338.471a, R 338.471b, R 338.472, R 338.473, R 338.473a, R 338.473b, R 338.473c, R 338.473d, R 338.474, R 338.474a, R 338.475, R 338.477, R 338.477a, R 338.477b, R 338.477c, R 338.477d, R 338.478, R 338.479, R 338.479a, R 338.479b, R 338.479c, R 338.480, R 338.480a, R 338.481, R 338.482, R 338.489, R 338.490, R 338.493a, R 338.493b, R 338.493c, R 338.493d, R 338.493f, R 338.493g, and R 338.500 of the Code are rescinded; and, R 338.501, R 338.503, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.539, R 338.551, R 338.553, R 338.555, R 338.557, R 338.559, R 338.561, R 338.563, R 338.565, R 338.567, R 338.569, R 338.571, R 338.573, R 338.575, R 338.577, R 338.582, R 338.583, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590 are added to the Code to read as follows:

PART 1. GENERAL PROVISIONS

R 338.471 ~~Repealer.~~ **Rescinded.**

~~Rule 1. All rules and regulations previously adopted by the state board of pharmacy, hereinafter referred to as the board, are hereby repealed and set aside.~~

R 338.471a ~~Definitions~~ **Rescinded.**

~~Rule 1a. As used in these rules:~~

~~(a) "Accredited college or school of pharmacy" means a college or school of pharmacy that is accredited by or has candidate status by the accreditation council for pharmacy education, as provided in R 338.474(1)(a).~~

~~(b) "Board" means the board of pharmacy.~~

~~(c) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.~~

March 5, 2019

- ~~(d) "Department" means the department of licensing and regulatory affairs.~~
- ~~(e) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.~~
- ~~(f) "Manual signature" means a signature that is handwritten or computer-generated if a prescription is electronically transmitted as defined in section 17703 of the code.~~
- ~~(g) "Program of practical pharmacy experience" means professional and clinical instruction in, but not limited to, all of the following areas:~~
- ~~(i) Pharmacy administration and management.~~
- ~~(ii) Drug distribution, use, and control.~~
- ~~(iii) Legal requirements.~~
- ~~(iv) Providing health information services and advising patients.~~
- ~~(v) Pharmacist's ethical and professional responsibilities.~~
- ~~(vi) Drug and product information.~~
- ~~(h) "Unconventional internship" means an educational program of professional and practical experience involving those pharmacy or related pharmaceutical experiences which, by practical, on-the-job training, provide knowledge useful to the practice of the profession of pharmacy without meeting all of the criteria of a conventional internship.~~

R 338.471b ~~Training standards for identifying victims of human trafficking; requirements.~~
Rescinded.

~~Rule 1b. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual seeking licensure or who is licensed shall complete training in identifying victims of human trafficking that meets the following standards:~~
- ~~(a) Training content must cover all of the following:~~
- ~~(i) Understanding the types and venues of human trafficking in the United States.~~
- ~~(ii) Identifying victims of human trafficking in health care settings.~~
- ~~(iii) Identifying the warning signs of human trafficking in health care settings for adults and minors.~~
- ~~(iv) Resources for reporting the suspected victims of human trafficking.~~
- ~~(b) Acceptable providers or methods of training include any of the following:~~
- ~~(i) Training offered by a nationally recognized or state-recognized, health-related organization.~~
- ~~(ii) Training offered by, or in conjunction, with a state or federal agency.~~
- ~~(iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.~~
- ~~(iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer reviewed journal, health care journal, or professional or scientific journal.~~
- ~~(c) Acceptable modalities of training may include any of the following:~~
- ~~(i) Teleconference or webinar.~~
- ~~(ii) Online presentation.~~
- ~~(iii) Live presentation.~~
- ~~(iv) Printed or electronic media.~~

~~- (2) The department may select and audit a sample of individuals and request documentation of proof of completion of training. If audited by the department, an individual shall provide an acceptable proof of completion of training, including either of the following:~~
~~- (a) Proof of completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.~~
~~- (b) A self certification statement by an individual. The certification statement must include the individual's name and either of the following:~~
~~- (i) For training completed pursuant to subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.~~
~~- (ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer review journal, health care journal or professional or scientific journal, and date, volume, and issue of publication as applicable.~~
~~- (3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning with the first renewal cycle after the promulgation of this rule and for initial licenses issued 5 or more years after the promulgation of this rule.~~

R 338.472 ~~Prescription drugs and devices; return or exchange for resale prohibited.~~
~~- Rule 2. (1) For the protection of the public health and safety, prescription drugs or devices which have been dispensed and which have left the control of the pharmacist shall not be returned or exchanged for resale.~~ **Rescinded.**
~~- (2) Subrule (1) of this rule does not apply to a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail that has accepted a prescription drug for resale or redispensing, as provided under section 17766d of the code.~~
~~- (3) Subrule (1) of this rule does not apply to a pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided under section 17775 of the code.~~

R 338.473 ~~Intern licensure; eligibility; limitations.~~ **Rescinded.**
~~- Rule 3. (1) An applicant for a pharmacy intern license shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall establish that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).~~
~~- (2) An intern shall engage in the practice of pharmacy only under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist.~~

R 338.473a ~~Interns; eligibility; limited license; qualifications; supervision; notice of position change; duties; professional and practical experience; denial, suspension, or revocation of license.~~ **Rescinded.**
~~- Rule 3a. (1) An individual is eligible for intern licensure at the beginning of the first professional year of study in an accredited college or school of pharmacy.~~
~~- (2) Upon application and payment of appropriate fees, a limited license shall be issued by the department to qualified applicants.~~

- (3) The limited license shall be renewed annually and shall remain active while the applicant is actively pursuing a degree in an accredited college or school of pharmacy and until the applicant is licensed as a pharmacist, or for not more than 1 year from the date of graduation from the pharmacy program.
- (4) An intern shall annually submit verification to the department that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).
- (5) An intern shall complete not less than 1,600 hours of internship experience. An intern working in this state shall hold an intern license in order to earn the hours of internship experience required in this state. The minimum number of hours of internship experience may be satisfied by complying with any of the following provisions:
- (a) Obtaining the minimum number of hours of experience under the personal charge of a qualified, approved preceptor.
- (b) Completing a structured practical experience program within the college or school of pharmacy curriculum.
- (c) Through a combination of subdivisions (a) and (b) of this subrule.
- (6) When eligible, a student shall apply for licensure as an intern.
- (7) Hours of internship experience shall be computed from the date of board certification as a licensed intern. In computing the hours of internship experience, all of the following provisions shall apply:
- (a) Experience shall be granted only upon verification by an approved pharmacy preceptor or other person previously approved by the board.
- (b) The board may grant internship experience gained in unconventional internship programs. Up to 400 hours of internship experience may be granted for such unconventional education experiences.
- (c) A maximum of 40 hours of internship experience shall be granted per calendar week served by the intern.
- (d) A maximum of 16 hours of non-college-sponsored internship experience shall be granted per calendar week while the intern is a full-time student in a college or school of pharmacy, except during authorized vacation periods.
- (e) The board may grant credit for internship experience obtained through practice as an intern in another jurisdiction if the experience was comparable to the minimum standards in these rules.
- (f) The board may accept experience as a licensed pharmacist in another state or Canada as the equivalent of internship experience.
- (8) The intern shall be responsible for verifying board approval of his or her pharmacy preceptor, required under R 338.473(2).
- (9) Within 30 days, an intern shall notify the board if he or she is no longer actively enrolled in a pharmacy degree program at an accredited college or school of pharmacy.
- (10) Interns shall complete and submit such forms or examinations, or both, as deemed necessary by the board.
- (11) Interns shall receive professional and practical experience in at least all of the following areas:
- (a) Pharmacy administration and management.
- (b) Drug distribution, use, and control.
- (c) Legal requirements.
- (d) Providing health information services and advising patients.

- ~~(e) Pharmacists' ethical and professional responsibilities.~~
- ~~(f) Drug and product information.~~
- ~~(12) Interns shall keep abreast of current developments in the internship program and the pharmacy profession.~~
- ~~(13) The board may deny, suspend, or revoke the license of an intern or may deny hours of internship for failure to comply with pharmacy law or rules relating to pharmacy practice or internship.~~

R 338.473b ~~Examinations adoption.~~ **Rescinded.**
- ~~Rule 3b. (1) The north American pharmacist licensure examination and the Michigan multi-state pharmacy jurisprudence examination that are developed, administered, and scored by the national association of boards of pharmacy (nabp) shall be the examinations for applicants seeking licensure.~~
- ~~(2) The passing score established by nabp for the north American pharmacist licensure examination and the Michigan multi-state pharmacy jurisprudence examination shall be the accepted score for licensure.~~

R 338.473c ~~Preceptors; approval; qualifications; duties; denial, suspension, or revocation of preceptor approval.~~ **Rescinded.**
- ~~Rule 3c. (1) Before training an intern, a licensed pharmacist in this state shall apply to the board for approval as a preceptor. A pharmacist shall have at least 1 year of practice before being approved as a preceptor.~~
- ~~(2) There shall be not more than 2 interns per pharmacist on duty at the same time. However, the approved preceptor is responsible for the overall internship program at the pharmacy.~~
- ~~(3) A preceptor is responsible for arranging the intern's training in areas of practice as defined in R 338.473a(9).~~
- ~~(4) A preceptor shall annually submit internship training affidavits on forms provided by the board.~~
- ~~(5) The preceptor shall determine the degree of professional skill possessed by the intern and shall develop a training program whereby the intern will be able to improve upon and develop his or her ability in the practice of pharmacy.~~
- ~~(6) The preceptor shall allow sufficient time to instruct the intern in the practice of pharmacy and to frequently review and discuss his or her progress.~~
- ~~(7) Upon completion of the intern training, the preceptor under whom the training was obtained shall give the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the board may require further training before allowing the intern to take the examination for licensure as required by R 338.474.~~
- ~~(8) The board may deny, suspend, or revoke the preceptor's approval for failure to properly supervise the intern during the internship training program or for violation of the laws and rules relating to the practice of pharmacy or the internship program.~~
- ~~(9) The board may deny, suspend, or revoke the preceptor's approval of a pharmacist who has been convicted of any violation of a federal, state, or local law, ordinance, or rules relating to pharmacy practice within 5 years of the application for approval as a preceptor.~~

R 338.473d ~~Graduates of a non-accredited college or school of pharmacy; requirements; internship.~~ **Rescinded.**

~~- Rule 3d. (1) An applicant who is a graduate of a non-accredited college or school of pharmacy may be granted an intern license to comply with the requirements of R 338.473a(5) upon making application, payment of appropriate fees, and providing evidence of successful completion of the foreign pharmacy graduate examination committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056.~~

~~- (2) The limited license shall be renewed annually. The limited license shall remain active while the applicant is actively completing the requirements of R 338.473a(5), and until the applicant is licensed as a pharmacist.~~

R 338.474 ~~Pharmacist licensure; eligibility; examination.~~ **Rescinded.**

~~- Rule 4. (1) An applicant for licensure as a pharmacist shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall comply with all of the following requirements:~~

~~- (a) Have completed the requirements for a degree in pharmacy from an accredited college or school of pharmacy education or successfully completed the foreign pharmacy graduate examination committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056. The standards and guidelines of the Accreditation Council for Pharmacy Education as set forth in the "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree", effective February 14, 2011, are adopted by reference in these rules. Copies of the standards are available at no cost from the Council's website at http://www.acpe-accredit.org/standards. Copies of the guidelines also are available for inspection and distribution at cost from the Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.~~

~~- (b) Have completed a program of internship pursuant to these rules.~~

~~- (c) Pass the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.~~

~~- (d) Pass an examination, under R 338.473b, which measures an applicant's theoretical and practical knowledge of pharmacy.~~

~~- (2) An applicant who has not achieved a passing score on either of the examinations identified in subrule (1)(c) and (d) of this rule after 5 attempts may be reexamined only after meeting the requirements in R 338.474a.~~

~~- (3) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~

R 338.474a ~~Licensure; reexamination.~~ **Rescinded.**

~~- Rule 4a. (1) An applicant may take the examinations required by R 338.474(1)(c) and (d) not more than 5 times, except as provided in subrules (2) and (3) of this rule.~~

- (2) An applicant who has not received a passing score on an examination that measures his or her theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following:
- (a) Enrolled as a student in a pharmacy education program approved by the board.
- (b) Taken courses which would provide a thorough review of these areas failed on the applicant's most recent examination.
- (c) Submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.
- (3) An applicant who has not received a passing score on the jurisprudence examination, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy, after 5 attempts, shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.

R 338.475 Licensure by endorsement; examination. **Rescinded.**
- Rule 5. (1) An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and administrative rules promulgated pursuant thereto, an applicant shall satisfy both of the following requirements:
- (a) Pass the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.
- (b) Establish that the applicant is currently licensed in another state and was initially licensed by examination in another state.
- (2) An applicant who has not received a passing score on the jurisprudence examination after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.
- (3) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.

R 338.477 Pharmacy licenses; applications; notice of changes; self-inspection reports. **Rescinded.**
- Rule 7. (1) Each separate pharmacy location where drugs are prepared or dispensed shall be licensed by the board under section 17741 of the code. If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required.
- (2) A licensee who is moving to a new location shall apply and be approved for a new license for each location before moving. The department shall provide license applications. A licensee shall pay a license fee to the department for each new location.
- (3) An applicant that is a partnership or corporation or that operates under an assumed name shall file, with its application for a pharmacy license, certified copies of its partnership certificates, corporate articles, or assumed name certificate. This requirement shall be waived

~~if the application is for additional units and the additional units will be under the same ownership.~~
~~- (4) A partnership, corporation, or entity operating under an assumed name shall provide the board with written notification of a change in any of the following entities:~~
~~- (a) Partners.~~
~~- (b) Stockholders.~~
~~- (c) Officers.~~
~~- (d) Members of the board of directors.~~
~~- (e) The individual pharmacist who is designated as the pharmacy licensee of a licensed pharmacy.A partnership or corporation shall notify the board within 30 days of the change.A publicly held corporate pharmacy need not report changes in stockholders.~~
~~- (5) A person who applies for a new pharmacy license or pharmacy relocation shall send an application and a completed self-inspection report on forms provided by the department.~~

R 338.477a ~~Application for license by governmental entity.~~ **Rescinded.**
~~- Rule 7a. An application by a governmental entity for a new or renewal pharmacy, drug manufacturer's, or wholesaler's license shall designate an individual to be the licensee. That individual and the pharmacist on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy.~~

R 338.477b ~~Requirements for relicensure; license lapsed for less than 3 years.~~ **Rescinded.**
~~- Rule 7b. (1) An applicant for relicensure who has had a lapsed license for less than 3 years, under the provisions of section 16201(3) of the code, may be relicensed by complying with both of the following requirements:~~
~~- (a) Submitting a completed application on a form provided by the department, together with the requisite fee.~~
~~- (b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.~~
~~- (2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~

R 338.477c ~~Requirements for relicensure; license lapsed for at least 3 years but not more than 8 years.~~ **Rescinded.**
~~- Rule 7c. (1) An applicant for relicensure who has had a lapsed license for at least 3 years but not more than 8 years, under the provisions of sections 16201(4) and 17733 of the code may be relicensed by complying with all of the following requirements:~~
~~- (a) Submitting a completed application on a form provided by the department, together with the requisite fee.~~
~~- (b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.~~

- ~~(c) Passing the jurisprudence examination under R338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.~~
- ~~(d) Completing within 6 months of applying for relicensure a program of practical pharmacy experience, as defined in R 338.471a(g), that is not less than 200 clock hours in length and that complies with both of the following:~~
- ~~(i) Requires an applicant to practice under the personal charge of a currently licensed pharmacist.~~
- ~~(ii) Requires the supervising pharmacist, when an applicant has completed the required practical experience, to provide the board with verification of the applicant's completion of the experience.~~
- ~~(2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~
- ~~(3) An applicant who has not received a passing score on the jurisprudence examination after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.~~
- ~~(4) For purposes of complying with subrule (1)(d) of this rule, an applicant may be granted a temporary, nonrenewable license to complete the practical experience.~~

R 338.477d ~~Requirements for relicensure; license lapsed for at least 8 years.~~ **Rescinded.**

- ~~Rule 7d. (1) An applicant for relicensure who has had a lapsed license for at least 8 years, under sections 16201(4) and 17733 of the code, may be relicensed by complying with all of the following requirements:~~
- ~~(a) Submitting a completed application on a form provided by the department, together with the requisite fee.~~
- ~~(b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.~~
- ~~(c) Passing the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.~~
- ~~(d) Completing, within 6 months of applying for relicensure a program of practical pharmacy experience, as defined in R 338.471a(g), that is not less than 400 clock hours in length and that complies with both of the following:~~
- ~~(i) Requires an applicant to practice under the personal charge of a currently licensed pharmacist.~~
- ~~(ii) Requires the supervising pharmacist, when an applicant has completed the required practical experience, to provide the board with verification of the applicant's completion of the experience.~~
- ~~(e) Passing an examination under R 338.473b, which measures an applicant's theoretical and practical knowledge of pharmacy.~~
- ~~(2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not~~

LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

Filed with the Secretary of State on

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

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145, 16148, **16174, 16175, 16178, 16182, 16186, 17722, 17731, 17737, 17746, 17748, 17748a, 17748b, 17751, 17753, 17757, 17760,** and ~~17721~~ **17767** of 1978 PA 368, MCL 333.16145, 333.16148, **333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.17722, 333.17731, 333.17737, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17751, 333.17753, 333.17757, 333.17760,** and ~~333.17721~~ **333.17767**, and Executive Order Nos. 1991-9, 1996-2, ~~2003-01~~ **2003-1**, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and MCL 445.2030)

R 338.486 of the Michigan Administrative Code is amended; and R 338.471, R 338.471a, R 338.471b, R 338.472, R 338.473, R 338.473a, R 338.473b, R 338.473c, R 338.473d, R 338.474, R 338.474a, R 338.475, R 338.477, R 338.477a, R 338.477b, R 338.477c, R 338.477d, R 338.478, R 338.479, R 338.479a, R 338.479b, R 338.479c, R 338.480, R 338.480a, R 338.481, R 338.482, R 338.489, R 338.490, R 338.493a, R 338.493b, R 338.493c, R 338.493d, R 338.493f, R 338.493g, and R 338.500 of the Code are rescinded; and, R 338.501, R 338.503, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.539, R 338.551, R 338.553, R 338.555, R 338.557, R 338.559, R 338.561, R 338.563, R 338.565, R 338.567, R 338.569, R 338.571, R 338.573, R 338.575, R 338.577, R 338.582, R 338.583, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590 are added to the Code to read as follows:

PART 1. GENERAL PROVISIONS

R 338.471 ~~Repealer.~~ **Rescinded.**

~~Rule 1. All rules and regulations previously adopted by the state board of pharmacy, hereinafter referred to as the board, are hereby repealed and set aside.~~

R 338.471a ~~Definitions~~ **Rescinded.**

~~Rule 1a. As used in these rules:~~

~~(a) "Accredited college or school of pharmacy" means a college or school of pharmacy that is accredited by or has candidate status by the accreditation council for pharmacy education, as provided in R 338.474(1)(a).~~

~~(b) "Board" means the board of pharmacy.~~

~~(c) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.~~

March 5, 2019

- (d) "Department" means the department of licensing and regulatory affairs.
- (e) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.
- (f) "Manual signature" means a signature that is handwritten or computer-generated if a prescription is electronically transmitted as defined in section 17703 of the code.
- (g) "Program of practical pharmacy experience" means professional and clinical instruction in, but not limited to, all of the following areas:
- (i) Pharmacy administration and management.
- (ii) Drug distribution, use, and control.
- (iii) Legal requirements.
- (iv) Providing health information services and advising patients.
- (v) Pharmacist's ethical and professional responsibilities.
- (vi) Drug and product information.
- (h) "Unconventional internship" means an educational program of professional and practical experience involving those pharmacy or related pharmaceutical experiences which, by practical, on-the-job training, provide knowledge useful to the practice of the profession of pharmacy without meeting all of the criteria of a conventional internship.

R 338.471b Training standards for identifying victims of human trafficking; requirements.
Rescinded.

Rule 1b. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual seeking licensure or who is licensed shall complete training in identifying victims of human trafficking that meets the following standards:
- (a) Training content must cover all of the following:
- (i) Understanding the types and venues of human trafficking in the United States.
- (ii) Identifying victims of human trafficking in health care settings.
- (iii) Identifying the warning signs of human trafficking in health care settings for adults and minors.
- (iv) Resources for reporting the suspected victims of human trafficking.
- (b) Acceptable providers or methods of training include any of the following:
- (i) Training offered by a nationally recognized or state-recognized, health-related organization.
- (ii) Training offered by, or in conjunction, with a state or federal agency.
- (iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.
- (iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer reviewed journal, health care journal, or professional or scientific journal.
- (c) Acceptable modalities of training may include any of the following:
- (i) Teleconference or webinar.
- (ii) Online presentation.
- (iii) Live presentation.
- (iv) Printed or electronic media.

~~- (2) The department may select and audit a sample of individuals and request documentation of proof of completion of training. If audited by the department, an individual shall provide an acceptable proof of completion of training, including either of the following:~~
~~- (a) Proof of completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.~~
~~- (b) A self-certification statement by an individual. The certification statement must include the individual's name and either of the following:~~
~~- (i) For training completed pursuant to subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.~~
~~- (ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer-review journal, health care journal or professional or scientific journal, and date, volume, and issue of publication as applicable.~~
~~- (3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning with the first renewal cycle after the promulgation of this rule and for initial licenses issued 5 or more years after the promulgation of this rule.~~

R 338.472 ~~Prescription drugs and devices; return or exchange for resale prohibited.~~
~~- Rule 2. (1) For the protection of the public health and safety, prescription drugs or devices which have been dispensed and which have left the control of the pharmacist shall not be returned or exchanged for resale.~~ **Rescinded.**
~~- (2) Subrule (1) of this rule does not apply to a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail that has accepted a prescription drug for resale or redispensing, as provided under section 17766d of the code.~~
~~- (3) Subrule (1) of this rule does not apply to a pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided under section 17775 of the code.~~

R 338.473 ~~Intern licensure; eligibility; limitations.~~ **Rescinded.**
~~- Rule 3. (1) An applicant for a pharmacy intern license shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall establish that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).~~
~~- (2) An intern shall engage in the practice of pharmacy only under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist.~~

R 338.473a ~~Interns; eligibility; limited license; qualifications; supervision; notice of position change; duties; professional and practical experience; denial, suspension, or revocation of license.~~ **Rescinded.**
~~- Rule 3a. (1) An individual is eligible for intern licensure at the beginning of the first professional year of study in an accredited college or school of pharmacy.~~
~~- (2) Upon application and payment of appropriate fees, a limited license shall be issued by the department to qualified applicants.~~

- (3) The limited license shall be renewed annually and shall remain active while the applicant is actively pursuing a degree in an accredited college or school of pharmacy and until the applicant is licensed as a pharmacist, or for not more than 1 year from the date of graduation from the pharmacy program.
- (4) An intern shall annually submit verification to the department that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).
- (5) An intern shall complete not less than 1,600 hours of internship experience. An intern working in this state shall hold an intern license in order to earn the hours of internship experience required in this state. The minimum number of hours of internship experience may be satisfied by complying with any of the following provisions:
- (a) Obtaining the minimum number of hours of experience under the personal charge of a qualified, approved preceptor.
- (b) Completing a structured practical experience program within the college or school of pharmacy curriculum.
- (c) Through a combination of subdivisions (a) and (b) of this subrule.
- (6) When eligible, a student shall apply for licensure as an intern.
- (7) Hours of internship experience shall be computed from the date of board certification as a licensed intern. In computing the hours of internship experience, all of the following provisions shall apply:
- (a) Experience shall be granted only upon verification by an approved pharmacy preceptor or other person previously approved by the board.
- (b) The board may grant internship experience gained in unconventional internship programs. Up to 400 hours of internship experience may be granted for such unconventional education experiences.
- (c) A maximum of 40 hours of internship experience shall be granted per calendar week served by the intern.
- (d) A maximum of 16 hours of non-college-sponsored internship experience shall be granted per calendar week while the intern is a full-time student in a college or school of pharmacy, except during authorized vacation periods.
- (e) The board may grant credit for internship experience obtained through practice as an intern in another jurisdiction if the experience was comparable to the minimum standards in these rules.
- (f) The board may accept experience as a licensed pharmacist in another state or Canada as the equivalent of internship experience.
- (8) The intern shall be responsible for verifying board approval of his or her pharmacy preceptor, required under R 338.473(2).
- (9) Within 30 days, an intern shall notify the board if he or she is no longer actively enrolled in a pharmacy degree program at an accredited college or school of pharmacy.
- (10) Interns shall complete and submit such forms or examinations, or both, as deemed necessary by the board.
- (11) Interns shall receive professional and practical experience in at least all of the following areas:
- (a) Pharmacy administration and management.
- (b) Drug distribution, use, and control.
- (c) Legal requirements.
- (d) Providing health information services and advising patients.

- ~~(e) Pharmacists' ethical and professional responsibilities.~~
- ~~(f) Drug and product information.~~
- ~~(12) Interns shall keep abreast of current developments in the internship program and the pharmacy profession.~~
- ~~(13) The board may deny, suspend, or revoke the license of an intern or may deny hours of internship for failure to comply with pharmacy law or rules relating to pharmacy practice or internship.~~

R 338.473b ~~Examinations adoption.~~ **Rescinded.**
- ~~Rule 3b. (1) The north American pharmacist licensure examination and the Michigan multi-state pharmacy jurisprudence examination that are developed, administered, and scored by the national association of boards of pharmacy (nabp) shall be the examinations for applicants seeking licensure.~~
- ~~(2) The passing score established by nabp for the north American pharmacist licensure examination and the Michigan multi-state pharmacy jurisprudence examination shall be the accepted score for licensure.~~

R 338.473c ~~Preceptors; approval; qualifications; duties; denial, suspension, or revocation of preceptor approval.~~ **Rescinded.**
- ~~Rule 3c. (1) Before training an intern, a licensed pharmacist in this state shall apply to the board for approval as a preceptor. A pharmacist shall have at least 1 year of practice before being approved as a preceptor.~~
- ~~(2) There shall be not more than 2 interns per pharmacist on duty at the same time. However, the approved preceptor is responsible for the overall internship program at the pharmacy.~~
- ~~(3) A preceptor is responsible for arranging the intern's training in areas of practice as defined in R 338.473a(9).~~
- ~~(4) A preceptor shall annually submit internship training affidavits on forms provided by the board.~~
- ~~(5) The preceptor shall determine the degree of professional skill possessed by the intern and shall develop a training program whereby the intern will be able to improve upon and develop his or her ability in the practice of pharmacy.~~
- ~~(6) The preceptor shall allow sufficient time to instruct the intern in the practice of pharmacy and to frequently review and discuss his or her progress.~~
- ~~(7) Upon completion of the intern training, the preceptor under whom the training was obtained shall give the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the board may require further training before allowing the intern to take the examination for licensure as required by R 338.474.~~
- ~~(8) The board may deny, suspend, or revoke the preceptor's approval for failure to properly supervise the intern during the internship training program or for violation of the laws and rules relating to the practice of pharmacy or the internship program.~~
- ~~(9) The board may deny, suspend, or revoke the preceptor's approval of a pharmacist who has been convicted of any violation of a federal, state, or local law, ordinance, or rules relating to pharmacy practice within 5 years of the application for approval as a preceptor.~~

R 338.473d ~~Graduates of a non-accredited college or school of pharmacy; requirements; internship.~~ **Rescinded.**

~~- Rule 3d. (1) An applicant who is a graduate of a non-accredited college or school of pharmacy may be granted an intern license to comply with the requirements of R 338.473a(5) upon making application, payment of appropriate fees, and providing evidence of successful completion of the foreign pharmacy graduate examination committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056.~~

~~- (2) The limited license shall be renewed annually. The limited license shall remain active while the applicant is actively completing the requirements of R 338.473a(5), and until the applicant is licensed as a pharmacist.~~

R 338.474 ~~Pharmacist licensure; eligibility; examination.~~ **Rescinded.**

~~- Rule 4. (1) An applicant for licensure as a pharmacist shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall comply with all of the following requirements:~~

~~- (a) Have completed the requirements for a degree in pharmacy from an accredited college or school of pharmacy education or successfully completed the foreign pharmacy graduate examination committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056. The standards and guidelines of the Accreditation Council for Pharmacy Education as set forth in the "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree", effective February 14, 2011, are adopted by reference in these rules. Copies of the standards are available at no cost from the Council's website at http://www.acpe-accredit.org/standards. Copies of the guidelines also are available for inspection and distribution at cost from the Michigan Board of Pharmacy, Department of Licensing and Regulatory Affairs, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.~~

~~- (b) Have completed a program of internship pursuant to these rules.~~

~~- (c) Pass the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.~~

~~- (d) Pass an examination, under R 338.473b, which measures an applicant's theoretical and practical knowledge of pharmacy.~~

~~- (2) An applicant who has not achieved a passing score on either of the examinations identified in subrule (1)(c) and (d) of this rule after 5 attempts may be reexamined only after meeting the requirements in R 338.474a.~~

~~- (3) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~

R 338.474a ~~Licensure; reexamination.~~ **Rescinded.**

~~- Rule 4a. (1) An applicant may take the examinations required by R 338.474(1)(c) and (d) not more than 5 times, except as provided in subrules (2) and (3) of this rule.~~

~~- (2) An applicant who has not received a passing score on an examination that measures his or her theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following:~~
~~- (a) Enrolled as a student in a pharmacy education program approved by the board.~~
~~- (b) Taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination.~~
~~- (c) Submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.~~
~~- (3) An applicant who has not received a passing score on the jurisprudence examination, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy, after 5 attempts, shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.~~

R 338.475 ~~Licensure by endorsement; examination.~~ **Rescinded.**
~~- Rule 5. (1) An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and administrative rules promulgated pursuant thereto, an applicant shall satisfy both of the following requirements:~~
~~- (a) Pass the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.~~
~~- (b) Establish that the applicant is currently licensed in another state and was initially licensed by examination in another state.~~
~~- (2) An applicant who has not received a passing score on the jurisprudence examination after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.~~
~~- (3) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~

R 338.477 ~~Pharmacy licenses; applications; notice of changes; self-inspection reports.~~ **Rescinded.**
~~- Rule 7. (1) Each separate pharmacy location where drugs are prepared or dispensed shall be licensed by the board under section 17741 of the code. If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required.~~
~~- (2) A licensee who is moving to a new location shall apply and be approved for a new license for each location before moving. The department shall provide license applications. A licensee shall pay a license fee to the department for each new location.~~
~~- (3) An applicant that is a partnership or corporation or that operates under an assumed name shall file, with its application for a pharmacy license, certified copies of its partnership certificates, corporate articles, or assumed name certificate. This requirement shall be waived~~

~~if the application is for additional units and the additional units will be under the same ownership.~~
~~- (4) A partnership, corporation, or entity operating under an assumed name shall provide the board with written notification of a change in any of the following entities:~~
~~- (a) Partners.~~
~~- (b) Stockholders.~~
~~- (c) Officers.~~
~~- (d) Members of the board of directors.~~
~~- (e) The individual pharmacist who is designated as the pharmacy licensee of a licensed pharmacy.A partnership or corporation shall notify the board within 30 days of the change.A publicly held corporate pharmacy need not report changes in stockholders.~~
~~- (5) A person who applies for a new pharmacy license or pharmacy relocation shall send an application and a completed self-inspection report on forms provided by the department.~~

R 338.477a ~~Application for license by governmental entity.~~ **Rescinded.**
~~- Rule 7a. An application by a governmental entity for a new or renewal pharmacy, drug manufacturer's, or wholesaler's license shall designate an individual to be the licensee. That individual and the pharmacist on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy.~~

R 338.477b ~~Requirements for relicensure; license lapsed for less than 3 years.~~ **Rescinded.**
~~- Rule 7b. (1) An applicant for relicensure who has had a lapsed license for less than 3 years, under the provisions of section 16201(3) of the code, may be relicensed by complying with both of the following requirements:~~
~~- (a) Submitting a completed application on a form provided by the department, together with the requisite fee.~~
~~- (b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.~~
~~- (2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~

R 338.477c ~~Requirements for relicensure; license lapsed for at least 3 years but not more than 8 years.~~ **Rescinded.**
~~- Rule 7c. (1) An applicant for relicensure who has had a lapsed license for at least 3 years but not more than 8 years, under the provisions of sections 16201(4) and 17733 of the code may be relicensed by complying with all of the following requirements:~~
~~- (a) Submitting a completed application on a form provided by the department, together with the requisite fee.~~
~~- (b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.~~

- (c) Passing the jurisprudence examination under R338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.
- (d) Completing within 6 months of applying for relicensure a program of practical pharmacy experience, as defined in R 338.471a(g), that is not less than 200 clock hours in length and that complies with both of the following:
- (i) Requires an applicant to practice under the personal charge of a currently licensed pharmacist.
- (ii) Requires the supervising pharmacist, when an applicant has completed the required practical experience, to provide the board with verification of the applicant's completion of the experience.
- (2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.
- (3) An applicant who has not received a passing score on the jurisprudence examination after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.
- (4) For purposes of complying with subrule (1)(d) of this rule, an applicant may be granted a temporary, nonrenewable license to complete the practical experience.

R 338.477d Requirements for relicensure; license lapsed for at least 8 years. **Rescinded.**
- Rule 7d. (1) An applicant for relicensure who has had a lapsed license for at least 8 years, under sections 16201(4) and 17733 of the code, may be relicensed by complying with all of the following requirements:
- (a) Submitting a completed application on a form provided by the department, together with the requisite fee.
- (b) Submitting proof of having completed 30 hours of continuing education in courses and programs, as provided under R 338.3043, that was earned within the 2-year period immediately preceding the application for relicensure.
- (c) Passing the jurisprudence examination under R 338.473b, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy.
- (d) Completing, within 6 months of applying for relicensure a program of practical pharmacy experience, as defined in R 338.471a(g), that is not less than 400 clock hours in length and that complies with both of the following:
- (i) Requires an applicant to practice under the personal charge of a currently licensed pharmacist.
- (ii) Requires the supervising pharmacist, when an applicant has completed the required practical experience, to provide the board with verification of the applicant's completion of the experience.
- (e) Passing an examination under R 338.473b, which measures an applicant's theoretical and practical knowledge of pharmacy.
- (2) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified by the licensing agency of another state of the United States in which the applicant holds a current license or ever held a license as a pharmacist. This includes, but is not

~~limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~
~~- (3) An applicant who has not received a passing score on the jurisprudence examination after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has completed a college course on jurisprudence.~~
~~- (4) An applicant who has not received a passing score on an examination that measures his or her theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following:~~
~~- (a) Has enrolled as a student in an accredited pharmacy education program.~~
~~- (b) Has taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination.~~
~~- (c) Has submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.~~
~~- (5) For purposes of complying with subrule (1)(d) of this rule, an applicant may be granted a temporary, nonrenewable license to complete the practical experience.~~

R 338.478 ~~"Person" defined.~~ **Rescinded.**
~~- Rule 8. The word "person," as used in all statutes, rules, and regulations relating to the profession of pharmacy, shall be construed to include individuals, partnerships, firms, corporations, associations, and governmental institutions.~~

R 338.479 ~~Prescription drug labeling and dispensing.~~ **Rescinded.**
~~- Rule 9. (1) All labeling of prescription drugs shall comply with the requirements of the code and the federal food, drug, and cosmetic act, 21 U.S.C. §301 et seq.~~
~~- (2) All containers in which prescription medication is dispensed shall bear a label which contains, at a minimum, all of the following information:~~
~~- (a) Pharmacy name and address.~~
~~- (b) Prescription number.~~
~~- (c) Patient's name.~~
~~- (d) Date the prescription was most recently dispensed.~~
~~- (e) Prescriber's name.~~
~~- (f) Directions for use.~~
~~- (g) The name of the medication and the strength, unless the prescriber indicates "do not label."~~
~~- (h) The quantity dispensed, if applicable.~~
~~- (i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."~~
~~- (3) If a drug is dispensed that is not the brand prescribed, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label shall indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This subrule does not apply if the prescriber indicates "do not label."~~
~~- (4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed shall be noted on the prescription.~~
~~- (5) This rule does not apply to inpatient medical institution service.~~

R 338.479a ~~Prescription drug receipts.~~ **Rescinded.**

~~- Rule 9a. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt which contains all of the following information:~~

~~- (a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."~~

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

~~- (c) The strength of the drug, if significant, unless the prescribed indicates "do not label."~~

~~- (d) The quantity dispensed, if applicable.~~

~~- (e) The name and address of the pharmacy.~~

~~- (f) The serial number of the prescription.~~

~~- (g) The date the prescription was most recently dispensed.~~

~~- (h) The name of the prescriber.~~

~~- (i) The name of the patient for whom the drug was prescribed.~~

~~- (j) The price for which the drug was sold to the purchaser.~~

~~- (2) Notwithstanding R 338.479, the information mandated in this rule shall appear on either the prescription label or on a combination label and receipt.~~

~~- (3) For prescription services that are covered by a third-party pay contract, the price included in the receipt is the amount actually paid by the patient.~~

~~- (4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule in the automated data processing system or on the written prescription form and the retention of the form constitutes retaining a copy of the receipt. The physical presence of the prescription form in the pharmacy or the ability to retrieve the information from the automated data processing system constitutes compliance with the requirement of having the name and address of the pharmacy on the form.~~

~~- (5) This rule does not apply to inpatient medical institution service.~~

R 338.479b ~~Noncontrolled prescriptions.~~ **Rescinded.**

~~- Rule 9b. (1) A prescriber who issues a prescription for a noncontrolled legend drug shall date the prescription; provide a manual signature on the prescription, as defined in R 338.471a(f) of these rules; and ensure that the prescription contains all of the following information:~~

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

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

~~- (c) The drug name and strength.~~

~~- (d) The quantity prescribed.~~

~~- (e) The directions for use.~~

~~- (f) The number of refills authorized.~~

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

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

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

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

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

- ~~(5) A noncontrolled substance prescription may be transmitted electronically from the prescriber to the pharmacy of the patient's choice, and shall occur by utilizing a system that includes the following:~~
- ~~(a) A combination of technical security measures such as, but not limited to, those listed in R 164.312 under Subpart C—Security Standards for the Protection of Electronic Protected Health Information of 45 CFR Part 164 that implements the federal health insurance portability and accountability act of 1996, to ensure all of the following:~~
- ~~(i) Authentication of an individual who prescribes or dispenses.~~
- ~~(ii) Technical non-repudiation.~~
- ~~(iii) Content integrity.~~
- ~~(iv) Confidentiality.~~
- ~~(b) An electronic signature as defined in R 338.471a(e). An electronic signature is valid when it is used to sign a noncontrolled prescription.~~
- ~~(c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.~~
- ~~(6) The electronic prescription shall meet any other requirements of the federal health insurance portability and accountability act.~~
- ~~(7) The electronic prescription shall permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:~~
- ~~(i) The indication that no substitute is allowed, such as "dispense as written" or "DAW".~~
- ~~(ii) The indication that no substitute is allowed and that it is a unique element in the prescription.~~
- ~~(8) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription shall identify the name of the pharmacy intended to receive the transmission, and shall include the information identified in subrule (1) of this rule.~~
- ~~(9) The electronic prescription shall be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription shall be made available to an authorized agent of the board upon request. A secured copy shall be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and shall be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.~~
- ~~(10) An electronic signature that meets the requirements of this rule shall have the full force and effect of a handwritten signature on a paper-based written prescription.~~
- ~~(11) A pharmacy shall keep the original prescription record for 5 years. After 3 years, a pharmacy may make an electronic duplicate of the original paper prescription, which shall become the original prescription. A pharmacy shall present a paper copy of the electronic duplicate of the prescription to an authorized agent of the board upon request.~~
- ~~(12) This rule does not apply to inpatient medical institutions.~~

R 338.479c ~~Customized patient medication packages (CPMP).~~ **Rescinded.**

~~Rule 9c. (1) In place of dispensing 2 or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package which is prepared by a pharmacist for a specific patient and which contains 2 or more prescribed solid oral dosage~~

forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken. The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.

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

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

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

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

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

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

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

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

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

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

- (b) A CPMP shall be accompanied by a patient package insert in case any medication in the CPMP is required to be dispensed with an insert as accompanying labeling. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

- (c) In the absence of more stringent packaging requirements for any of the drug products contained in the CPMP, each CPMP shall be in compliance with the United States pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, for moisture permeation requirements for a class b single- unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened. All provisions of the poison prevention packaging act, as defined in section 17761(2) of the code, shall be complied with.

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

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

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

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

- (iv) The drug products require special packaging.

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

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

- ~~(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed shall be made and filed. At a minimum each record, shall contain all of the following information:~~
- ~~(i) The name and address of the patient.~~
- ~~(ii) The serial number of the prescription order for each drug product contained in the CPMP.~~
- ~~(iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.~~
- ~~(iv) The date of preparation of the CPMP and the expiration date assigned.~~
- ~~(v) Any special labeling instructions.~~
- ~~(vi) The name or initials of the pharmacist who prepared the CPMP.~~

R 338.480 ~~Prescription records; nonapplicability to inpatient medical institution service.~~ **Rescinded.**

- ~~Rule 10. (1) A prescription shall be numbered, dated, and initialed or electronically initialed by the pharmacist who performs the final verification prior to dispensing at the time of the first filling at the pharmacy.~~
- ~~(2) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.~~
- ~~(3) This rule does not apply to inpatient medical institution service.~~

R 338.480a ~~Prescription refill records; manual systems; profile systems; automated data processing systems; nonapplicability to inpatient medical institution service; record confidentiality and access.~~ **Rescinded.**

- ~~Rule 10a. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.~~
- ~~(2) A pharmacy may utilize a manual system of recording refills if the system is in compliance with both of the following criteria:~~
- ~~(a) The amount and date dispensed shall be entered on the prescription in an orderly fashion and the dispensing pharmacist shall initial the entry.~~
~~If the pharmacist only initials and dates the prescription, then the full face amount of the prescription shall be deemed dispensed.~~
- ~~(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.~~
- ~~(3) A pharmacy may utilize a uniform system of recording refills if the system is in compliance with all of the following criteria:~~
- ~~(a) Records shall be created and maintained in written form. All original and refill prescription information for a particular prescription shall appear on single documents in an organized format. The pharmacy shall preserve the records for 5 years. The records are subject to inspection by the board or its agents.~~
- ~~(b) All of the following information for each prescription shall be entered on the record:~~
- ~~(i) The prescription number.~~
- ~~(ii) The patient's name and address.~~

- ~~(iii) The prescriber's name.~~
- ~~(iv) The prescriber's federal drug enforcement administration number, if appropriate.~~
- ~~(v) The number of refills authorized.~~
- ~~(vi) The "dispense as written" instructions, if indicated.~~
- ~~(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.~~
- ~~(viii) The date of issuance of the prescription.~~
- ~~(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.~~
- ~~(c) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and shall initial the record each time a prescription is filled or refilled.~~
- ~~(d) The information required by subdivision (b) of this subrule shall be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.480.~~
- ~~(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system is in compliance with all of the following criteria:~~
- ~~(a) All information that is pertinent to a prescription shall be entered on the record, including all of the following information:~~
- ~~(i) The prescription number.~~
- ~~(ii) The patient's name and address.~~
- ~~(iii) The prescriber's name.~~
- ~~(iv) The prescriber's federal drug enforcement administration number, if appropriate.~~
- ~~(v) The number of refills authorized.~~
- ~~(vi) Whether the drug must be dispensed as written.~~
- ~~(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.~~
- ~~(viii) The date of issuance of the prescription.~~
- ~~(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.~~
- ~~(b) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the~~
~~information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy shall preserve the records on-site for 5 years. The records are subject to inspection by the board or its agents. A procedure shall be established to facilitate inspections.~~

- (c) The required information shall be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.480.
- (d) The recording system shall provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records.
- (e) The recording system shall have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trial for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other required information shall be made available to an authorized agent of the board upon request. The prescription data shall be maintained for 5 years. Data older than 16 months shall be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current 16 months shall be readily retrievable on site and available for immediate review.
- (f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.
- (g) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records.
- (h) The automated data processing system shall be an integrated system that is capable of complying with all of the requirements of these rules.
- (5) This rule does not apply to inpatient medical institution service.
- (6) Records that are created under subrule (3) or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

R 338.481 Professional and technical equipment and supplies. **Rescinded.**

- Rule 11. (1) A pharmacy shall be equipped with necessary drawers, shelves, storage cabinets, and prescription files. A sink that has hot and cold running water and a refrigerator of reasonable capacity shall be in the pharmacy department.
- (2) A pharmacy shall have current editions or revisions of the Michigan pharmacy laws and rules and not less than 2 current or revised pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. A current electronic medium version of the pharmacy laws, rules, and pharmacy reference texts, including accessible internet versions, meets the requirements of this subrule.
- (3) A pharmacy shall have the necessary equipment to dispense prescription drugs.

R 338.482 Housing of pharmacy. **Rescinded.**

- Rule 12. (1) All professional and technical equipment and supplies and prescription drugs shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings.
- (2) All pharmacies shall have a prescription department which is devoted primarily to the practice of pharmacy which occupies not less than 150 square feet of space, and which includes a

~~prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist who is on duty at any one time, the free working space shall be increased by not less than 4 square feet. The prescription counter shall be kept clean and orderly. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.~~

~~(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall be permanently enclosed by partitions from the floor to the ceiling. All partitions shall be of substantial construction and shall be securely lockable so that drugs and devices that can only be sold by a pharmacist are unobtainable during the absence of the pharmacist. Identification of this department by the use of the words "drug," "medicines," or "pharmacy" or by the use of a similar term or combination of terms, as defined in MCL 333.17711(2), shall be restricted to the area that is licensed by the board. The pharmacy department shall be locked when the pharmacist is not on the premises.~~

~~ADMINISTRATIVE HEARINGS~~

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

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

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

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

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

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

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

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

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

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

A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

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

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

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

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

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

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

~~(i)~~ **(j)** Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist ~~shall~~ **must** be available on an on-call basis. Only a limited number of medications that are packaged in units of use ~~shall~~ **must** be available. The medications ~~shall~~ **must** be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication ~~shall~~ **must** be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication ~~shall~~ **must** be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document ~~shall~~ **must** be obtained for each medication ~~united~~ **unit** removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

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

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient, or a unique identifier, ~~shall~~ **must** be labeled on the medication container. The container may be the individual ~~patients'~~ **patient's** assigned medication drawer. The directions for use ~~shall~~ **must** be on the label of the container if the directions are not

communicated in another effective manner. If the medication is to be self-administered, then directions for use ~~shall~~ **must** be on the container. The ~~preceding~~ provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

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

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

R 338.489 ~~Automated devices.~~ **Rescinded.**

~~- Rule 19. (1) An automated device means a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription.~~

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

~~- (a) A pharmacy.~~

~~- (b) A hospital.~~

~~- (c) A county medical care facility.~~

~~- (d) A hospice.~~

~~- (e) A nursing home.~~

~~- (f) Other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109.~~

~~- (g) An office of a dispensing prescriber.~~

~~- (3) An automated device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription, as defined in the code, and located within a licensed pharmacy shall be used only by a pharmacist or other pharmacy personnel under the personal charge of a pharmacist.~~

~~- (4) If an automated dispensing device is used in a dispensing prescriber's office, the device shall be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office.~~

~~- (a) If a dispensing prescriber delegates the stocking of the device, then technologies shall 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, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the dispensing prescriber for review by an agent of the board. This documentation shall include at least all of the following information:~~

~~- (i) Manufacturer name and model.~~

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

- (iii) Policy and procedures for system operation that addresses at a minimum all of the following:
- (A) Accuracy.
- (B) Patient confidentiality.
- (C) Access.
- (D) Data retention or archival records.
- (E) Downtime procedures.
- (F) Emergency procedures.
- (G) Medication security.
- (H) Quality assurance.
- (5) An automated device that is to be used for the furnishing of medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in 1978 PA 368, MCL 333.20109, shall be supplied and controlled by a pharmacy that is licensed and located in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the device, then technologies shall 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.Each such device shall comply with all of the following provisions:
- (a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.
- (b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the pharmacy for review by an agent of the board. The documentation shall include at least all of the following information:
- (i) Name and address of the pharmacy responsible for the operation of the automated device.
- (ii) Name and address of the facility where the device is located.
- (iii) Manufacturer name and model number.
- (iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.
- (v) Policy and procedures for system operation that address at a minimum all of the following:
- (A) Accuracy.
- (B) Patient confidentiality.
- (C) Access.
- (D) Data retention or archival records.
- (E) Downtime procedures.
- (F) Emergency procedures.
- (G) Medication security.
- (H) Quality assurance.
- (I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.
- (6) Records and electronic data kept by automated devices shall meet all of the following requirements:

- ~~(a) All events involving access to the contents of the automated devices shall be recorded electronically.~~
- ~~(b) Records shall be maintained for 5 years by the pharmacy and shall be retrievable on demand for review by an agent of the board. The records shall include all of the following information:~~
- ~~(i) The unique identity of device accessed.~~
- ~~(ii) Identification of the individual accessing the device.~~
- ~~(iii) The type of transaction.~~
- ~~(iv) The name, strength, dosage form and quantity 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 device.~~
- ~~(7) Policy and procedures for the use of the automated device shall 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)(i).~~
- ~~(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(e).~~
- ~~(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)(e). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.~~
- ~~(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.~~
- ~~(e) The device is located in a dispensing prescriber's office.~~
- ~~(8) A copy of all policies and procedures related to the use of an automated device shall 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.~~

R 338.490 ~~Professional responsibility; "caregiver" defined.~~ **Rescinded.**

- ~~Rule 20. (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 or from other lawful channels of distribution.~~
- ~~(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:~~
- ~~(a) The prescription appears to be improperly written.~~
- ~~(b) The prescription is susceptible to more than 1 interpretation.~~
- ~~(c) The pharmacist has reason to believe that the prescription could cause harm to the patient.~~
- ~~(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.~~
- ~~(3) A prescription drug shall only be dispensed when the pharmacy is open and under the personal charge of a pharmacist.~~
- ~~(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate, to the patient or the patient's caregiver, necessary and appropriate information regarding safe and~~

effective medication use at the time a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient's care. All of the following provisions apply to communicating medication safety and effectiveness information:

- (a) The information shall 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 material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.
- (b) The information shall be provided with each prescription for a drug not previously prescribed for the patient.
- (c) If the pharmacist deems it appropriate, the information shall be provided with prescription refills.
- (d) The information shall be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.
- (5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code and under the personal charge of the delegating pharmacist, except as provided in R 338.486(3). A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person shall do all of the following:
- (a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.
- (b) Before delegating an act, task, or function, make a determination that the delegatee has the necessary knowledge and skills to safely and competently complete the act, task, or function.
- (c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.
- (d) Supervise and evaluate the performance of the delegatee.
- (e) Provide remediation of the performance of the delegatee if indicated.
- (6) A delegating pharmacist shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

PART 2. MANUFACTURING AND DISTRIBUTION OF PRESCRIPTION DRUGS

R 338.493a Applicability; distributions by pharmacies; license requirements. **Rescinded.**

- Rule 23a. (1) These rules apply to a manufacturer or wholesale distributor that is licensed to do business in this state on or after September 1, 1992, or that applies for a license to do business in this state on or after September 1, 1992.
- (2) If the total number of dosage units of all prescription drugs that are distributed by a pharmacy to a person as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the 12-month period, then the pharmacy is a wholesale distributor as defined in section 17709(2) of the code.

- ~~(3) If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code.~~
- ~~(4) A manufacturer or wholesale distributor that distributes prescription drugs in Michigan only from a location outside of Michigan shall obtain a license to do business in Michigan. A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in Michigan from 1 or more locations in Michigan shall obtain a separate license for each location in Michigan where prescription drugs are manufactured or distributed.~~

R 338.493b ~~Manufacturing practice; adoption by reference of standards.~~ **Rescinded.**
- ~~Rule 23b. (1) A manufacturer shall maintain the building, operate the equipment, and administer the controls, records, and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions of 21 C.F.R. 211.1 to 211.208, (April 1, 2013). The criteria set forth in the provisions of 21 C.F.R. 211.1 to 211.208 are adopted in these rules by reference. Copies of the adopted material are available from the Superintendent of Documents, United States Government Printing Office, Washington, DC 20402, at cost or from the Board of Pharmacy, Department of Licensing and Regulatory Affairs, P.O. Box 30018, Lansing, Michigan 48909, at cost.~~
- ~~(2) A manufacturer shall comply with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner.~~

R 338.493c ~~Wholesaling practice; minimum requirements.~~ **Rescinded.**
- ~~Rule 23c. A wholesale distributor shall maintain and comply with all of the following minimum standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records:~~
- ~~(a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall be in compliance with all of the following provisions:~~
- ~~(i) Be of a suitable size and construction to facilitate cleaning, maintenance, and proper operations.~~
- ~~(ii) Have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.~~
- ~~(iii) Have a quarantine area for the storage of prescription drugs which are outdated, damaged, deteriorated, misbranded, or adulterated or which are in immediate or sealed secondary containers that have been opened.~~
- ~~(iv) Be maintained in a clean and orderly condition.~~
- ~~(v) Be free from infestation by insects, rodents, birds, or vermin of any kind.~~
- ~~(b) All facilities that are used for wholesale drug distribution shall be secure from unauthorized entry as specified in the following provisions:~~

- (i) Access from outside the premises shall be kept to a minimum and be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (ii) All facilities shall be equipped with an alarm system to detect entry after hours.
- (iii) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (c) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with label requirements or in accordance with requirements set forth in the current edition of the official compendium. If storage requirements are not established for a prescription drug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document the proper storage of prescription drugs. The recordkeeping requirements in subdivision (f) of this rule shall be followed for all stored prescription drugs.
- (d) All of the following provisions apply to the examination of materials:
- (i) Each outside shipping container shall be visually examined upon receipt for the identity of the prescription drug products and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damages to the contents.
- (ii) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that prescription drugs that have been damaged in storage or held under improper conditions are not delivered.
- (iii) The recordkeeping requirements in subdivision (f) of this rule shall be followed for all incoming and outgoing prescription drugs.
- (e) All of the following provisions apply to returned, damaged, and outdated prescription drugs:
- (i) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
- (ii) Any immediate or sealed outer or sealed secondary containers of any prescription drugs that have been opened or used shall be identified as such and the drugs shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
- (iii) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

- ~~(iv) The recordkeeping requirements of subdivision (f) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.~~
- ~~(f) All of the following provisions apply to recordkeeping:~~
- ~~(i) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include all of the following information:~~
- ~~(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.~~
- ~~(b) The identity and quantity of the drugs received and distributed or disposed of.~~
- ~~(c) The dates of receipt and distribution or other disposition of the drugs.~~
- ~~(ii) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of 2 years after disposition of the drugs.~~
- ~~(iii) Records which are described in this subdivision and which are kept at the inspection site or can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records which are kept at a central location apart from the inspection site and which are not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a federal, state, or local law enforcement agency.~~
- ~~(g) Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include all of the following procedures in their written policies and procedures:~~
- ~~(i) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedures may permit deviation from this requirement if the deviation is temporary and appropriate.~~
- ~~(ii) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to any of the following:~~
- ~~(a) Any action initiated at the request of the food and drug administration, the board, or other federal, state, or local law enforcement agency or other government agency.~~
- ~~(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.~~
- ~~(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.~~
- ~~(iii) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other situations of local, state, or national emergency.~~
- ~~(iv) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.~~

- (h) Wholesale distributors shall establish and maintain lists of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (i) Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner.
- (j) Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.
- (k) Each person employed in any prescription drug wholesale distribution activity shall have education, training and experience, or any combination of education, training and experience, sufficient for that person to perform the assigned functions in such a manner as to provide assurance
that the drug product quality, safety and security will at all times be maintained as required by law.

R 338.493d License application; manufacturers and wholesale distributors. **Rescinded.**
- Rule 23d. An application for a license as a manufacturer or wholesale distributor shall be made on a form provided by the department and shall contain all of the following information:
- (a) All names, addresses, and telephone numbers used by the applicant in this state.
- (b) State of incorporation.
- (c) The kind of ownership or operation, such as individually owned, partnership, association, cooperative, or corporation.
- (d) The name of the owner or operator, including, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporation officer and director.
- (e) A partnership, corporation, or an applicant who operates under an assumed name shall file certified copies of its partnership certificate, corporate articles, or assumed name certificate with its initial application.
- (f) A brief description of the buildings in this state that are owned, controlled, or used by the applicant in connection with, or for the manufacture or wholesale distribution of, prescription drugs, the address, if different from that of the principal address of the applicant, at which each building is located, and an indication of the type of activity or activities carried on in each building, such as any of the following:
- (i) The manufacture of active ingredients.
- (ii) Compounding.
- (iii) Packaging.
- (iv) Repackaging.
- (v) Operating a quality control laboratory.
- (vi) Recordkeeping and storage.
- (vii) Operating a sales office.
- (viii) Warehousing of ingredients.
- (ix) Warehousing of finished products for distribution.

~~(g) An applicant for a manufacturer's license shall also furnish information as to the formula and name or names of each prescription drug that is supplied or distributed under the manufacturer's label. An up-to-date catalog that contains information required by this subdivision may be supplied for this purpose.~~

R 338.493f ~~Inspection of applicants and licensees.~~ **Rescinded.**

~~Rule 23f. The board or a board inspector may enter, at reasonable times, any building, place, or facility which is owned or controlled by any applicant for, or holder of, a license to make an inspection which is reasonably necessary to enable the board to determine whether the applicant possesses the necessary qualifications and competence for the license sought or to determine whether a license holder is, and has been, complying with the acts and rules enforced by the board. The inspection shall be carried out in a reasonable manner and shall concern only matters relevant to the applicant's or license holder's manufacturing or wholesale distributing of drugs saleable on prescription only. The inspection shall not extend to any of the following information:~~

~~(a) Financial data.~~

~~(b) Sales data other than shipment data.~~

~~(c) Pricing data.~~

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

~~(e) Research data.~~

R 338.493g ~~Persons to whom drugs may be sold or distributed.~~ **Rescinded.**

~~Rule 23g. With respect to prescription drugs, a manufacturer or wholesale distributor shall only supply, distribute, sell, offer for sale, barter, or otherwise transfer drugs to persons who are licensed by the board or to persons who are licensed to prescribe drugs in this state.~~

~~PART 3. MEDICATION DRUG BOX EXCHANGE PROGRAMS FOR HOSPICE~~

R 338.500 ~~Hospice emergency drug box.~~ **Rescinded.**

~~Rule 30. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes pursuant to the provisions of section 17746 of the code shall establish drug boxes that are in compliance with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall assure that the hospice has developed policies and procedures that require all of the following:~~

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

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

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

~~(d) A procedure for implementing the hospice medical director's responsibility for assuring that prescriptions for drugs removed from the drug boxes are obtained from the attending physicians.~~

- (2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.
- (3) The drugs contained in each drug box shall be listed inside the front cover of the box. Each box shall be equipped with only 1 nonreuseable, tamper-evident seal or sealing system which is a color that designates that the box has not been opened and several nonreuseable, tamper-evident seals or sealing systems which are a different color that designates that the box has been opened.
- (4) The drug boxes shall be numbered. A permanent record of all drug boxes shall be maintained at the pharmacy.
- (5) A label that contains all of the following information shall be attached to the drug box so that it is visible from the outside of the box:
- (a) The name and address of the pharmacy.
- (b) The name and address of the hospice.
- (c) The name of the pharmacist who last inspected and restocked the drug box.
- (d) The date the drug box was last restocked.
- (e) The date on which the drug box must be returned to the pharmacy for the replacement of expired drugs.
- (f) The number of the drug box.
- (6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreuseable, tamper-evident seal or sealing system which is the color that designates that the box has not been opened.
- (7) The drug boxes shall be kept in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, registered nurse, or physician's assistant. The boxes shall be stored under conditions that will maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment shall be limited to individuals who are authorized to dispense drugs from a drug box on the order of an attending physician or the hospice medical director.
- (8) The drug box shall remain sealed at all times, except when in use. The drug box shall only be opened by a registered nurse or physician's assistant on the order of an attending physician or the medical director of the hospice. All drugs removed from the box shall be recorded on a medication use form. After completing the form, the registered nurse or physician's assistant shall place the form in the box and seal the box with a nonreuseable, tamper-evident seal or sealing system which is a color that designates that the box has been opened.
- (9) Each drug box under the control of the pharmacy shall be examined at least weekly to assure that the seal which designates that the box has not been opened is still intact and the expiration date has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box shall be returned to the pharmacy. When written prescriptions are required, the prescriptions of the attending physician or hospice medical director shall accompany the drug boxes that have been opened when the drug boxes are returned to the pharmacy.
- (10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record shall contain all of the following information:
- (a) The number of the box.
- (b) The name of the hospice to which the box is released.

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

R 338.501 Definitions.

Rule 1. (1) As used in these rules:

(a) "Approved education program" means a school of pharmacy that is accredited by or has candidate status by the Accreditation Council for Pharmacy Education.

(b) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(c) "Code" means public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

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

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

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

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

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

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

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

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

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

(f) "Department" means the department of licensing and regulatory affairs.

(g) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.

(h) "Manual signature" means a signature that is handwritten or computer-generated if a prescription is electronically transmitted as defined in section 17703(7) and (8) of the code, MCL 333.17703(7) and (8).

(i) "Practical experience" means professional and clinical instruction in, but not limited to, all of the following areas:

(i) Pharmacy administration and management.

(ii) Drug distribution, use, and control.
(iii) Legal requirements.
(iv) Providing health information services and advising patients.
(v) Pharmacist's ethical and professional responsibilities.
(vi) Drug and product information.
(vii) Evaluating drug therapies and preventing or correcting drug-related issues.
(j) "Virtual manufacturer" means a person who engages in the manufacture of prescription drugs or devices and meets all of the following:
(i) Owns either of the following:
(A) The new prescription drug application or abbreviated new prescription drug application number.
(B) The unique device identification number, as available, for a prescription device.
(ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices.
(iii) Is not involved in the physical manufacture of the drugs or devices.
(iv) At no time takes physical possession of or stores the drugs or devices.
(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.
(2) The terms defined in the code have the same meaning when used in these rules.

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.
Rule 3. (1) Prescription drugs or devices that have been dispensed and have left the control of the pharmacist must not be returned or exchanged for resale.
(2) This rule does not apply to any of the following:
(a) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail, as provided in section 17766d of the code, MCL 333.17766d.
(b) A pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided in section 17775 of the code, MCL 333.17775.
(c) A pharmacy or health facility that participates in the cancer drug repository program, as provided in section 17780 of the code, MCL 333.17780.

R 338. 505 Inspection of applicants and licensees.
Rule 5. The board, board inspector, board agent, or approved entity pursuant to R 338.532, may enter at reasonable times, any building, place, or facility that is owned or controlled by any applicant for, or holder of, a license to make an inspection to enable the board to determine if the applicant possesses the qualifications and competence for the license sought or to determine whether a license holder is and has been complying with the code and rules. The inspection must concern only matters relevant to the applicant's or license holder's practice of pharmacy, manufacturing, and wholesale distributing of drugs and devices saleable by prescription only.
(1) The inspection must not extend to any of the following information:
(a) Financial data.
(b) Sales data other than shipment data.
(c) Pricing data.

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

(e) Research data.

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

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

PART 2. PHARMACIST LICENSES

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

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

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

(i) Understanding the types and venues of human trafficking in the United States.

(ii) Identifying victims of human trafficking in health care settings.

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

(iv) Resources for reporting the suspected victims of human trafficking.

(b) Acceptable providers or methods of training include any of the following:

(i) Training offered by a nationally recognized or state-recognized, health-related organization.

(ii) Training offered by, or in conjunction, with a state or federal agency.

(iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.

(iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer reviewed journal, health care journal, or professional or scientific journal.

(c) Acceptable modalities of training may include any of the following:

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

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

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

(b) A self-certification statement by an individual. The certification statement must include the individual's name and either of the following:

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

(ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer review journal, health care journal or professional or scientific journal, and date, volume, and issue of publication as applicable.

(3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning in 2020 and for initial licenses issued after November 13, 2022.

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

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

(a) That he or she is actively enrolled in, or is within 90 days of having graduated from, an approved educational program.

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

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

(a) At the time of renewal, the applicant shall submit verification to the department that he or she is actively enrolled in, or is within 90 days of having graduated from, an approved educational program. The educational limited license is valid for 1 year.

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

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

(4) An educational limited licensee shall verify that his or her pharmacy preceptor holds a valid preceptor license prior to engaging in the practice of pharmacy.

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

R 338.515 Internship requirements.

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

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

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

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

Commented [A1]: Have concerns that "others" than who is named would be qualified to do this.

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

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

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

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)(i) and develop a training program whereby the intern can improve his or her skill in these areas.

(c) Ensure sufficient time to instruct the intern on the topics in R 338.501(1)(i) and review and discuss the intern's progress on the topics in R 338.501(1)(i).

(d) Annually submit training affidavits and, upon completion of the training, provide comments regarding the ability of the intern to practice pharmacy without supervision on a form provided by the department.

R 338.519 Examinations adoption; passing scores; reexamination.

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

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

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

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

Commented [A2]: This is more reasonable than after each failed exam and also aligns with the "3 exam 12-month" cap outlined in (5).

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

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

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

R 338.521 Pharmacist licensure by examination.

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

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

(a) Earned either of the following:

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

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

(b) Successfully passed the MPJE and the NAPLEX.

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

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

Commented [A3]: This is the old name of ACPE - the rules should reflect the current name (Accreditation Council for Pharmacy Education).

Commented [A4]: This organization uses a different set of criteria than ACPE.

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.

(2) An applicant shall satisfy all of the following requirements:

(a) Establish that the he or she is currently licensed in another state and was initially licensed by examination in another state.

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

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

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

R 338.525 Relicensure of a pharmacist license; requirements.

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

(1) For a pharmacist who has let his or her license lapse and who is not currently licensed in another state:	License lapsed 0-3 years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years

(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		X	X
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure.	X	X	X
(e) Pass MPJE: retake and pass the MPJE as provided in R 338.519.		X	X
(f) Practical experience: complete 200 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.		X	
(g) Practical experience: complete 400 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.			X
(h) Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
(i) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the applicant.	X	X	X

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

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

(4) For a pharmacist who has let his or her pharmacist license lapse, but who holds a current and valid pharmacist license in another state:	License lapsed 0-3 Years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		X	X
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure.	X	X	X
(e) Examination: retake and pass the MPJE as provided in R 338.519.		X	X
(e) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant holds or has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the applicant.	X	X	X

PART 3. PHARMACY LICENSES

R 338.531 Pharmacy license; applications; requirements.

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

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

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

(b) Submission of fingerprints for the purpose of a criminal history background check required under section 17748(6) of the code, MCL 333.17748(6).
(c) Proof of registration or licensure from every state or province where the pharmacy is currently licensed or has ever held a license or registration.
(d) The name and license number of the pharmacist in this state designated as the pharmacist in charge (PIC) pursuant to section 17748(2) of the code, MCL 333.17748(2), who must have a valid and unrestricted license.
(e) The identity and address of each partner, officer, or owner, as applicable.
(f) A completed self-inspection form.
(g) If the applicant intends to provide sterile compounding services, proof of application with an entity that satisfies the requirements of R 338.532.
(h) An inspection report that satisfies the requirements of R 338.534.
(i) If the applicant is an in-state pharmacy that intends to compound sterile pharmaceutical products, the applicant shall submit to an inspection from an approved accrediting organization under R 338.532.
(j) If the applicant is a governmental entity, an individual must be designated as the licensee. The licensee and the pharmacist on duty shall be responsible for complying with all federal and state laws regulating the practice of pharmacy and the dispensing of prescription drugs.
(3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared or dispensed, each address location shall obtain a separate license.
(4) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. This includes, but is not limited to, USP Chapters 795 and 800.
(a) The standards adopted by reference in subrule (4) of this rule are available at cost at http://www.usp.org/compounding, or at cost from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.
(b) A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule.

R 338.532 Sterile compounding accrediting organizations; board approval; inspection entities.
Rule 32. (1) The board shall approve, under section 17748a of the code, MCL 333.17748a, accrediting organizations or inspection entities for pharmacies that compound sterile pharmaceuticals according to standards adopted by reference in R 338.533.
(2) The department shall post on its website, the list of organizations approved under subrule (1) of this rule.
(3) An organization may petition the board for approval under subrule (1) of this rule. The petition must include, but not be limited to, all of the following:
(a) Requirements for accreditation or compliance.
(b) Requirements for inspectors.
(c) Training provided to inspectors.
(d) Copy of the most current inspection form.

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

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

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

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

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

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

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

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

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

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

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

Commented [A5]: "Supervision" is not a defined term in the Code or the rules. The Code and rules generally use "personal charge" in reference to needing the immediate presence of a pharmacist.

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

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

(iv) Being certified by a compounding certification program approved by the board.

(d) Label compounded drugs with all of the following:

(i) Required drug and ingredient information.

(ii) Facility identification.
(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."
(e) Ensure that bulk drug substances used for sterile compounding meet specified FDA criteria.
(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.

R 338.534 Inspections.
Rule 34. (1) A pharmacy located outside of this state that applies for licensure in this state as a pharmacy that will not ship compounded sterile pharmaceutical products into this state, shall submit to the department a copy of its most recent pharmacy inspection that was performed within the last 2 years.
(2) An applicant for a new pharmacy located in this state shall have an inspection conducted by the department or its designee prior to licensure.
(3) An applicant for licensure of a pharmacy that will provide sterile compounded pharmaceuticals shall have all of the following:
(a) An onsite physical inspection conducted by any of the following:
(i) The department.
(ii) The national association of boards of pharmacy verified pharmacy program (NABP-VPP).
(iii) An accrediting organization according to R 338.532.
(iv) A state licensing agency of the state in which the applicant is a resident and in accordance with the NABP's multistate pharmacy inspection blueprint program.
(b) A physical inspection and corresponding report completed within 18 months of application.
(c) A physical inspection and corresponding report that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533.
(4) An out-of-state pharmacy that intends to ship sterile compounded pharmaceutical products into this state shall obtain an inspection from the NABP, VPP, or the Joint Commission every 18 months.

Commented [A6]: The Board of Pharmacy also approved the Joint Commission on Aug. 10, 2016.

R 338.535 Discontinuing sterile compounding services; requirements to resume sterile compounding services.
Rule 35. (1) A sterile compounding pharmacy that ceases to provide sterile compounding services in this state shall notify the department within 30 days of ceasing to provide sterile compounding services.
(2) A pharmacy shall not resume providing sterile compounding services in this state until the pharmacy is approved by the department and is accredited or verifies that it is USP compliant by an organization satisfying the requirements of R 338.532(1).
(3) A pharmacy shall apply for approval to resume sterile compounding services by submitting to the department an application on a form provided by the department together with the requisite fee.

R 338.536 Housing of a pharmacy.

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

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

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

R 338.537 Professional and technical equipment and supplies.

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

(a) Drawers, shelves, and storage cabinets.

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

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

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

R 338.538 Closing pharmacy.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

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

R 338.539 Relicensure.

Rule 39. (1) An applicant for relicensure of a pharmacy license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) A pharmacy that has an expired license shall satisfy the requirements of R 338.531 to be relicensed.

PART 4. MANUFACTURER LICENSE

R 338.551 Manufacturer license; application.

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

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

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

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

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

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

(e) A completed compliance checklist for manufacturers.

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

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

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

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

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

R 338.553 Persons to whom prescription drugs or devices may be sold.

Rule 53. A manufacturer may only supply, distribute, sell, barter, or otherwise transfer prescription drugs or devices to persons who are licensed by the board to distribute, prescribe, or dispense prescription drugs or devices in or outside this state.

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 good manufacturing practice for finished pharmaceuticals regulations set forth in 21 C.F.R. sections 211.1 to 211.208 (1978).

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

R 338.557 Closure of a manufacturer.

Rule 57. (1) A manufacturer that is ceasing operations shall return the manufacturer license and the controlled substance license, if applicable, to the department, and provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

(2) A manufacturer shall comply with all applicable federal requirements for discontinuing a controlled substance business.

R 338.559 Relicensure.

Rule 59. (1) An applicant for relicensure of a manufacturer license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) A manufacturer that has an expired license shall satisfy the requirements of R 338.551 in order to be relicensed.

PART 5. WHOLESALE DISTRIBUTOR LICENSE

R 338.561 Pharmacy as wholesale distributor; licensure.

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

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

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

R 338.563 Wholesale distributor; application for licensure; requirements.

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

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

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

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

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

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

(e) A completed compliance checklist.

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

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

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

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

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

(1) A high school diploma.

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

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

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

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

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

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

(3) Knowledge and understanding of quality control systems.

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

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

(C) Experience equal to either of the following:

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

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

R 338.565 Persons to whom prescription drugs and devices may be sold.

Rule 65 A wholesale distributor of prescription drugs or devices may supply, distribute, sell, barter, or otherwise transfer prescription drugs or devices only to persons who are licensed by the board to distribute, prescribe, or dispense prescriptions drugs or devices in or outside this state.

R 338.567 Wholesale distributor practices; control of prescription drugs or devices; inspections.

Rule 67. (1) A wholesale distributor that does not physically touch prescription drugs or devices shall file an affidavit with the department signed by the PIC or facility manager attesting to this fact.

(2) A wholesale distributor that previously filed an affidavit under subrule (1) of this rule shall not obtain custody and control of drugs or devices until both of the following have occurred:

(a) The licensee provides written notification to the department of physical custody.

(b) The department conducts an inspection of the premises.

R 338.569 Wholesale distributor 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 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 whereby the oldest stock of a prescription drug is distributed first. The procedure may permit 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 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 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) The records described in subrules (1) and (2) of this rule must be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials. The records that are 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 subrule (5) of this rule. Records that are kept at a central location apart from the site must be made available for inspection within 2 working days of a request.

(5) The records described in this rule must be maintained for a minimum of 2 years after the disposition of the prescription drugs or devices.

R 338.571 Facility requirements.

Rule 71. (1) A wholesale distributor that has physical custody or control of the prescription drugs or devices shall satisfy all of the following facility requirements:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

(b) Have storage areas that are designed to provide for adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(c) Have a quarantine area for the storage of prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, adulterated, or that are in immediate or sealed secondary containers that have been opened.

(d) Be maintained in a clean and orderly condition.

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(f) Be secure from unauthorized entry by complying with all of the following:

(i) Access from outside the premises must be kept to a minimum and be well-controlled. The outside perimeter of the premises must be well-lighted. Entry into areas where prescription drugs or devices are held must be limited to authorized personnel.

(ii) Be equipped with an alarm system to detect entry after hours.

(iii) Be equipped with a security system that will provide protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) All prescription drugs or devices must be stored at temperatures and under appropriate conditions pursuant to the label requirements or pursuant to the requirements set forth in the current edition of the USP compendium. If storage requirements are not established for a prescription drug, the drug may be held at a controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment devices, or logs must be utilized to document the proper storage of prescription drugs or devices.

R 338.573 Examination of materials; returned, damaged and outdated prescription drugs or devices.

Rule 73. (1) A wholesale distributor shall comply with both of the following provisions that pertain to the examination of materials:

(a) Each outside shipping container must be visually examined upon receipt for the identity of the prescription drug or devices and to prevent the acceptance of contaminated prescription drugs or devices or prescription drugs or devices otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be visually inspected for identity of the prescription drug products and to ensure that prescription drugs or devices that have been damaged in storage or held under conditions that are inconsistent with USP compendium standards are not delivered.

(2) All of the following provisions apply to returned, damaged, and outdated prescription drugs or devices:

(a) Prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, must be quarantined and physically separated from other prescription drugs or devices until they are destroyed or returned to the supplier.

(b) Any immediate or sealed outer or sealed secondary containers of any prescription drugs or devices that have been opened or used must be identified as such and the drugs or devices must be quarantined and physically separated from other prescription drugs or devices until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(3) The recordkeeping requirements of R 338.569 must be followed.

R 338.575 Closing a wholesale distributor.

Rule 75. (1) A wholesale distributor that is ceasing operations shall return the wholesale distributor license and controlled substance license, if applicable, to the department, and shall provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of noncontrolled substances.

(d) The disposition of records and prescription files.

(2) A wholesale distributor shall comply with all applicable federal requirements for discontinuing a business that handles a controlled substance.

R 338.577 Relicensure.

Rule 77. (1) An applicant for relicensure of a wholesale distributor license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) An applicant for relicensure of a wholesale distributor license that has expired must satisfy the requirements of R 338.563 in order to be relicensed.

PART 6. PRACTICE OF PHARMACY

R 338.582 Prescription drug labeling and dispensing.

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

(2) All containers in which prescription medication is dispensed must bear a label that contains, at a minimum, all of the following information:
(a) Pharmacy name and address.
(b) Prescription number.
(c) Patient's name.
(d) Date the prescription was most recently dispensed.
(e) Prescriber's name.
(f) Directions for use.
(g) The name of the medication and the strength, unless the prescriber indicates "do not label."
(h) The quantity dispensed, if applicable.
(i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."
(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This subrule does not apply if the prescriber indicates "do not label."
(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed must be noted on the prescription.
(5) This rule does not apply to pharmacy services provided in a medical institution.

R 338.583 Prescription drug receipts.
Rule 83. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt that contains all of the following information:
(a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."
(b) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."
(c) The strength of the drug, if significant, unless the prescribed indicates "do not label."
(d) The quantity dispensed, if applicable.
(e) The name and address of the pharmacy.
(f) The serial number of the prescription.
(g) The date the prescription was most recently dispensed.
(h) The name of the prescriber.
(i) The name of the patient for whom the drug was prescribed.
(j) The price for which the drug was sold to the purchaser.
(2) Notwithstanding R 338.582, the information required in this rule must appear on either the prescription label or on a combination label and receipt.
(3) For prescription services that are covered by a third-party pay contract, the price included in the receipt is the amount paid by the patient.
(4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule in the automated data processing system or on the written prescription form and the retention of the form constitutes retaining a copy of the

receipt. The physical presence of the prescription form in the pharmacy or the ability to retrieve the information from the automated data processing system constitutes compliance with the requirement of having the name and address of the pharmacy on the form.

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

R 338.584 Noncontrolled prescriptions.

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

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

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

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

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

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

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

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

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

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

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

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

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

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

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

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

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

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

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

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

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

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

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

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

R 338.585 Customized patient medication package.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) The drug products require special packaging.

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

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

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

(i) The name and address of the patient.

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

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

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

(v) Any special labeling instructions.

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

R 338.586 Prescription records; nonapplicability to inpatient medical institution service. Rule 86. (1) A prescription must be numbered, dated, and initialed or electronically initialed by the pharmacist who performs the final verification prior to dispensing at the time of the first filling at the pharmacy.

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

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

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

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

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

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

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

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

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

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

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration (DEA) number, if appropriate.

(v) The number of refills authorized.

(vi) The "dispense as written" instructions, if indicated.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

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

(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.

(d) The information required by subdivision (b) of this subrule must be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.

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

(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal DEA number, if appropriate.

(v) The number of refills authorized.

(vi) Whether the drug must be dispensed as written.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

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

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

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

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

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

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

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy continues to have adequate and complete

prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall ensure continuity in the maintenance of records.

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

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

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

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.

(b) A hospital.

(c) A county medical care facility.

(d) A hospice.

(e) A nursing home.

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

(g) An office of a dispensing prescriber.

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

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

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

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

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

(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the dispensing prescriber for review by an agent of the board. This documentation must include at least all of the following information:

(i) Manufacturer name and model.

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

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

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

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

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

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

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

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

(iii) Manufacturer name and model number.

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

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

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

(f) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

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

(7) Records and electronic data kept by automated devices must meet all of the following requirements:

(a) All events involving access to the contents of the automated devices must be recorded electronically.

(b) Records must be maintained for 5 years by the pharmacy and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:

(i) The unique identifier of the automated device accessed.

(ii) Identification of the individual accessing the automated device.

(iii) The type of transaction.

(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.

(v) The name of the patient for whom the drug was ordered.

(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.

(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:

(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(j).

(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).

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

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

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

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

R 338.589 Professional responsibility; "caregiver" defined.

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

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

(a) The prescription appears to be improperly written.

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

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

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

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

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

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

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

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

(d) The information must be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.

Commented [A7]: A requirement to document the consultation (or the reason why consultation wasn't completed) should be included. There are a number of reasons for this ... not the least of which is to protect the pharmacist from liability should a patient claim he/she wasn't warned as required by this rule.

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

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

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

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

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

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

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

R 338.590 Hospice emergency drug box.

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

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

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

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

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

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

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

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

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

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

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

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

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

(f) The number of the drug box.

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

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

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

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

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

(a) The number of the box.

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

(c) The date the box is released to the hospice.

(d) The name and signature of the pharmacist who releases the box to the hospice.

(e) The expiration date assigned.

(f) The date the box is returned to the pharmacy for restocking.

(g) The name and signature of the pharmacist who received the box for restocking.

(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the attending physician or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed from the hospice drug box on the back of the prescriptions. The prescriptions must be filed in the same manner as other prescriptions are maintained at the pharmacy.

Deeb Eid, PharmD, RPh: Submitting comments on behalf of myself
Assistant Professor/Experiential Coordinator, Pharmacy Practice Department
Ferris State University College of Pharmacy
220 Ferris Drive, Big Rapids, MI 49307
deebeid@ferris.edu

Re: Public Comment on Pharmacy General Rules (ORR #2018-039 LR) & Continuing Education (ORR #2019-022 LR)

Dear Michigan Board of Pharmacy,

I'd like to first commend you on the rule promulgation and changes you have proposed in Michigan. In my opinion, you are taking steps needed to increase patient safety and help to remove barriers to care with these proposed rules. As part of a role in regulatory affairs, my service to the profession, an educator of future pharmacists, and an academic researcher, I've been tracking topics associated with the rule rewrites taking place and wanted to provide comments, questions, and feedback for your consideration.

Below are the comments I'd like to share with the Board for consideration:

Section: *General Provisions, R338.486 (a)*
Comments: Consider adding "home for the aged" to the definition of "Medical institution".
Language Example: (a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, freestanding surgical outpatient facility, hospice, **home for the aged,** or other health facility which that is licensed or approved by the state, and which directly or indirectly provides or includes pharmacy services.
Rationale: LARA itself has a division of Adult Foster Care and Homes for the Aged[1]. Include this would provide inclusivity.

Section: *Part 2 Pharmacist Licenses, R338.511, R338.513*
Comments: Does an educational limited license require the human trafficking training? Generally speaking, CE requirements don't apply for "student pharmacists" or "interns" since they are registered within a College of Pharmacy. This may not be clear with the current language.

Section: *Part 2 Pharmacist Licenses, R338.519(4)*
Comments: Consider removal of *(4)* or keep the current language from *R338.474a (1-3).*
Language Example: ~~(4) If an applicant for licensure fails to pass either of these examinations, he or she shall provide the board, after each failed attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.~~
Rationale: Considering NAPLEX national pass rates for 2018 were at 89.46% for first-time attempts and Michigan-based NAPLEX first-time attempt pass rate (92.59%) this rule

seems unnecessary. Michigan data indicates that approximately 10.54% of Michigan-based applicants would have had to re-take the NAPLEX. This also potentially places financial burden on a sizable portion (7.41-10.54%) of student pharmacists, with the cost of an approved education program. With national debt averages around $160,000 for student pharmacists, this is an additional cost acquired by citizens.

MPJE national pass rates for 2018 were at 83.76% for first-time attempts. Michigan-based MPJE first-attempt pass rate are around 92%. Approximately 12.24% of Michigan-based applicants would have to re-take the MPJE. This again potentially places financial burden on a sizable portion (8-12.24%) of student pharmacists, both in fees surrounding retaking the MPJE itself and with the cost of the approved education program.

Additionally, this proposed rule is an outlier when considering neighboring states such as Ohio and Indiana which have no such requirement. Illinois allows for three NAPLEX attempts before requiring remedial education through an approved program.

There is no sound evidence to demonstrate that adding in this educational requirement after each failure will improve passing rates.

Section: *Relicensure of a pharmacist license R338.525*
Comments: If CE hours are submitted within the application that do not meet the new requirements, what would this result in? Are the human trafficking training and opioid training required for relicensure or just a one-time requirement?

Section: *Part 3 Pharmacy Licenses R338.531*
Comments: If the pharmacist on record passes away, what happens to the pharmacy license? How often must inspections be submitted? Are details of an inspection required to be shared with the state to obtain a license? Are pharmacy license renewals treated similar?

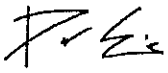
Section: *Part 6 Practice of Pharmacy, R338.582*
Comments: Although being worked on within the Pharmacy Technician specific rules, consider the following for both this section and the Pharmacy Technician rule set.

Tech-check-tech, or as some states are now calling it "accuracy checking" or "technician product verifiction" has been successfully and safely practiced in some states for decades. There are approximately 20 studies to date on the topic in various settings including community based and health systems. **Adams et al** reviewed and demonstrated safety data, including that results of 11 studies published since 1978 indicate that technicians' accuracy in performing final dispensing checks is very comparable to pharmacists' accuracy (mean ± S.D., **99.6%** ± 0.55% versus **99.3%** ± 0.68%, respectively. **Frost et al** also reviews data in the community setting and also showed that in 2 studies that reported accuracy rates, pharmacy technicians performed at least as accurately as pharmacists (**99.445** vs **99.73%**, P = .484; **99.95** vs **99.74**, P < .05). In addition, there are multiple pilot and research programs in states such as Wisconsin, Tennessee, Iowa, South Dakota, and more which have been studying the workflow

and outcomes of implementing these models. I encourage the board and other stakeholders to move forward on this as it will only help to improve patient care initiatives and allow for pharmacists to spend more time with patients as demonstrated by **Andreski et al**. I'd also encourage the board to refer to **Adams** for deliberations of the Idaho regulatory board on advancing technician practice, which an example from.

Section: *Continuing Education R338.3041 License Renewals*
Comments: Consider changing the requirement for "pain and symptom management" to "addiction and opioid harm reduction".
Rationale: The focus needs to shift from simply pain management topics to a broader area of addiction and harm reduction. Considering the impact of the opioid epidemic, fatalities, and many other areas, healthcare professionals would benefit from increasing their knowledge in a more broad area that is focused on addiction. This may help to bring about positive changes and equip practitioners with knowledge on fighting addiction and helping patients to improve.

Thanks for your consideration,



Deeb Eid, PharmD

Ditschman, Andria (LARA)

From: Justin <jkuhns@portagepharmacy.com>
Sent: Wednesday, October 02, 2019 12:24 PM
To: Ditschman, Andria (LARA)
Cc: Brad McCloskey
Subject: Comments to USP Rules
Attachments: Board of Pharmacy - CSP rules.docx

Hello Andria!

Attached you will find my comments to submit to the board regarding the general rules as it applies to compounding.

Thank you!

JUSTIN KUHNS, PHARM.D.
Lab Director
Portage Pharmacy
Phone: 269-492-7149
7966 Lovers Ln. Portage, MI 49002

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PCAB ACCREDITED
Compounding Pharmacy

R 338.531 Pharmacy license; applications; requirements.

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

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

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

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

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

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

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

(f) A completed self-inspection form.

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

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

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

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

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

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

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

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

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

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

(a) "Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.

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

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

(a) Requirements for accreditation or compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

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

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

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

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

(2) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP) Chapter 800 for entities engaged in compounding, preparing, or otherwise manipulating antineoplastic drugs.

(a) "Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.

(b) "Antineoplastic drugs" means substances identified as antineoplastic drugs by the National Institute of Occupational Safety and Health (NIOSH).

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

(4) A pharmacy, physician private office, dental private office, podiatric private office, veterinarian private office, infusion center, surgical outpatient facility, hospital, health facility, or outsourcing facility that provides ~~sterile~~ compounding services shall comply with all current standards adopted in subrule (1) and (2) of this rule.

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

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

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

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

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

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

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

(iv) Being certified by a compounding certification program approved by the board.

(d) Label compounded drugs with all of the following:

(i) Required drug and ingredient information.

(ii) Facility identification.

(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."

(e) Ensure that bulk drug substances used for ~~sterile~~ compounding meet specified FDA criteria.

(9) An outsourcing facility may compound drugs that appear on an FDA shortage list, if the bulk drug substances used to compound the drugs comply with the criteria specified in this rule.

(10) An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need.

(a) The term "Secretary" means the Secretary of Health and Human Services of the United States.

R 338.534 Inspections.

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

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

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

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

(i) The department.

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

(iii) An accrediting organization according to R 338.532.

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

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

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

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

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

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

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

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

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

Much

Much Shelist, P.C.
Attorneys at Law

191 N. Wacker Drive
Suite 1800
Chicago, IL 60606

312.521.2000
muchlaw.com

September 11, 2019

DIRECT DIAL: 312.521.2482
MOBILE: 312.656.4153
nmilenkovich@muchlaw.com

Via FedEx & Email (BPLHelp@michigan.gov)
Michigan Board of Pharmacy
Bureau of Professional Licensing/Licensing Division
611 W Ottawa, 3rd Floor
PO Box 30670
Lansing, MI 48909-8170

Re: USP GC <795> Nonsterile Compounding and Flavoring

To Whom It May Concern:

I am writing this letter as a legal representative of FLAVORx, a company that supplies custom-flavoring systems to pharmacies across the United States. I am also a licensed pharmacist, attorney, and father concerned about the impact USP's position will have on pediatric healthcare. I am writing to express my concern over a recent change implemented by USP regarding nonsterile compounding, and the impact it will have on the practice of pharmacy and pediatric healthcare in Michigan. USP recently indicated they intend to classify all flavoring of conventionally manufactured medications as nonsterile compounding. USP has taken this position despite the fact that flavorings are tested for potency and proven to be safe and inert when added to medications. The practice of flavoring medications has long been an integral and valuable part of the pharmacy profession, and USP's decision would effectively eliminate flavoring as an adherence boosting service for patients, which is currently utilized millions of times each year without a single reported incident. When community pharmacists need to obtain prescriber authorization and follow compounding procedural requirements to simply add a flavoring agent to conventionally manufactured medications, it is not surprising that pharmacies quickly discontinue offering the service to patients. Fourteen state boards of pharmacy already have language on their books excluding flavoring from the definition of compounding and not a single board has drafted regulations affirmatively recognizing flavoring as compounding.

As I'm sure you are aware, medication adherence is a critically important element of patient care and an essential determinant of clinical success. Studies conclusively show that the palatability of pediatric oral medications is one of the most critical factors influencing adherence to therapeutic regimens for children. Having children participate in flavoring their medications at their local pharmacy is a safe and proven mechanism for pharmacists to enhance medication palatability and is one of the best resources we have to support pediatric medication adherence.

To ensure community pharmacists and parents are able to continue utilizing this valuable service for pediatric patients in Michigan, I recommend the Board implement a regulation excepting the safe administration of flavoring from the definition of compounding. The Board can achieve this by narrowing the use of flavoring agents to conventionally manufactured

and commercially available liquid medications and by setting conditions to ensure safe administration of flavoring (e.g. flavoring agents must be nonallergenic and inert, not exceeding five (5) percent of a drug product's total volume). I am more than happy to assist the Board in crafting language that safeguards the quality and safety of flavoring agents without sacrificing their benefit to patients and the public health.

I appreciate your consideration in this matter. I respectfully request an in-person meeting or conference call at your earliest convenience, so we can discuss a common-sense resolution to this public health issue. I will contact your office to set up a mutually convenient date and time for this discussion.

Very truly yours,

Ned Milenkovich, PharmD, JD

SpartanNash

September 19, 2019

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
P.O. Box 30004
Lansing, MI 48909-8170
Attention: Policy Analyst

Via email: BPL-BoardSupport@michigan.gov

RE: Proposed Changes to the Pharmacy General Rules

Thank you for the opportunity to provide comment on the proposed changes in the Pharmacy – General Rules. SpartanNash is a retail pharmacy chain operating 63 pharmacies across Michigan and employing over 150 pharmacists practicing in the state. We appreciate this opportunity and your consideration of our feedback related to the proposed regulations.

Our comments on the proposed administrative rules are as follows:

Proposed Language: R338.513 (4) An educational limited licensee shall verify that his or her pharmacy preceptor holds a valid preceptor license prior to engaging in the practice of pharmacy.
Comment: In the context of the Proposed Rule 13, this subrule seems to require that an educational limited licensee (pharmacy intern) only practice under the direct personal supervision of a pharmacist licensed as a preceptor. Previously, this requirement only extended to pharmacy interns working towards the intern hours required to obtain their full pharmacist license. The language, as proposed, would create a barrier for pharmacy interns seeking to gain additional experience through paid internships aside from what is required by their academic programs. Also, this seems to conflict with Rule 15 (3) which creates provisions for a pharmacy intern to submit hours that were *not* conducted under the personal charge of a preceptor licensed in the state. As such, we recommend that Rule 13, Subrule (4) be removed from the rules as proposed.

Proposed Language: R338.531 (4) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. This includes, but is not limited to, USP Chapters 795 and 800. ... (b) A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule.
Comment: The adoption of these reference standards in conjunction with the clause in (4)(b) seems to imply that the standards are only applicable to pharmacies providing compounding services, though this is not explicit. Additionally, some of the guidance in the standards extend to practices beyond compounding and it is unclear as to whether pharmacies operating under

the purview of these standards would be required to comply with the full reference standard, or just the areas that apply to compounding practices. Additionally, recent comments at the NABP Annual meeting by a USP representative suggest that the USP's intent regarding general chapter <800> indicate that this guidance was intended to apply to compounding activities only. To provide additional clarification, we recommend that Rule 31, Subrule (4)(b) be modified to read: "A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule as they apply to compounding services as defined in Michigan law."

Proposed Language: R338.563 (2)(i)(B) Completion of a training program that includes, but is not limited to, all of the following subjects:
(1) Knowledge and understanding of laws in this state and federal laws relating to the distribution of drugs and devices.
(2) Knowledge and understanding of laws in this state and federal laws relating to the distribution of controlled substances.
(3) Knowledge and understanding of quality control systems.
(4) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.
(5) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.

Comment: While the training requirements under Rule 63, Subrule (2)(i)(B)are advisable to a person in the facility manager position, a lack of accredited or universally recognized training program makes the path to compliance with this rule unclear. Given that no accredited program exists, employers should have the discretion as to exactly what kind of training they require of an individual in this position absent a regulatory requirement. Additionally, Subrule (2)(i)(C) establishes experience requirements that should address any concerns as to whether a facility manager is qualified to fill their position. As such, we recommend that Subrule (2)(i)(C) and all requirements under this subrule by removed from the rules as proposed.

Proposed Language: R 338.588 (2) An automated device may be used only in the following locations:
(a) A pharmacy.
(b) A hospital.
(c) A county medical care facility.
(d) A hospice.
(e) A nursing home.
(f) Other skilled nursing facility as defined in section 20109(4) of the code, MCL 333.20109(4).
(g) An office of a dispensing prescriber.
(h) A location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, consistent with section 17760 of the code, MCL 333.17760.

Comment: Statutory changes that have occurred since the original rules regarding the use of automated devices in healthcare settings, as well as the addition of Subrule (2)(h) in these proposed rules, creates the potential for automated devices to be used in locations outside a pharmacy but at the same physical address of the pharmacy. However, this is currently limited only to hospital settings. Given that hospital pharmacies do not have any differentiation in license classification and, in some circumstances, have the ability to operate as outpatient facilities, this creates an environment where certain outpatient pharmacies are able to use these devices in capacities that are denied to pharmacies in the community practice setting. To address this discrepancy, we recommend that Rule 88, Subrule (2)(a) be modified to read:

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

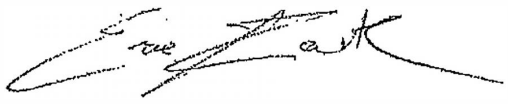
Proposed Language: R338.588 (3) A pharmacy that operates an automated device under this section shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.

Comment: The current definition "automated device" in the Michigan Public Health Code and in the rules as proposed encompasses several devices that may be used in workflow for tasks other than the delivery of a medication to patient or other healthcare provider (e.g., counting machines and packaging devices operated by pharmacy staff as part of the dispensing process). We feel that to register each of these devices with the department goes beyond the intent of the Board and the Department and will cause devices that do not require department oversight to be erroneously registered with the Department. To correct this, we recommend that Rule 88, Subrule (3) be modified to read: "A pharmacy that operates an automated device under this section to deliver a drug or device directly to a patient or other healthcare provider shall notify the department of the automated device's location on a form provided by the department..."

Proposed Language: R338.588 (7) Records and electronic data kept by automated devices must meet all of the following requirements:
(a) All events involving access to the contents of the automated devices must be recorded electronically.
(b) Records must be maintained for 5 years by the pharmacy and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:

Comment: To provide consistency in the record keeping requirements for pharmacies and dispensing prescribers, we recommend that Rule 88, Subrule (7)(b) be modified to read: "Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board..."

Respectfully submitted,



Eric Roath, PharmD, MBA
Clinical Care Coordinator
SpartanNash
1550 Gezon Parkway, Suite E-100
Wyoming, MI 49509
Phone: 616-878-2324 Fax: 616-878-8850

MICHIGAN PHARMACISTS ASSOCIATION

September 19, 2019

Andria M. Ditschman, JD,
Senior Analyst
Boards and Committees Section
Bureau of Professional Licensing
Michigan Department of Licensing and Regulatory Affairs
611 W. Ottawa Street
P.O. Box 30004
Lansing, Michigan 48909

Dear Andria,

Thank you for allowing the Michigan Pharmacists Association (MPA) the opportunity to comment on the draft rules for Pharmacy – General Rules. We appreciate the Board of Pharmacy's willingness to work with all stakeholders and look forward to more open dialogue between us. Below are the Michigan Pharmacists Association's comments on the draft rules at this time.

R 338.486 Rule 16 (3) Do not strike "who is on the premises."
R 338.501 Rule 1 (j) "Virtual Manufacturer" is not defined in statute and should be.
R 338.511 Rule 11 (3) Not consistent with proposed CE rules – consider same verbiage. CE Rules should use the same language.
R 338.513 Rule 13 (a) Remove "90 days" and replace with "180 days."
R 338.513 Rule 13 (3) Replace with "An educational limited licensee must engage in the practice of pharmacy under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist."
R 338.515 Rule 15 (c) Remove "or other person previously approved by the board."
R 338.515 Rule 15 (3) Remove "personal charge" replace with "supervision of."
R. 338.519 Rule 19 (4) After "examinations" add "within 3 attempts" after "after" add "the third."
R 338.521 Rule 21 (2) (i) Remove "Canadian council for accreditation of pharmacy programs." The Canadian Healthcare System is significantly different than that of the United States and should be removed from the rules.
R 338.525 Rule 25 (f) Remove "or outside of Michigan."
R 338.525 Rule 25 (g) Remove "or outside of Michigan."
R 338.531 Rule 31 (3) MPA recommends the language mirrors R 338.477 "If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required."
R 338.534 Rule 34 (1) Remove "ship" and replace with "distribute."
R 338.534 Rule 34 (4) Remove "ship" and replace with "distribute" remove "the NABP-VPP" replace with "a board approved accrediting organization."
R 338.559 Rule 59 MPA believes that R 338.493a(3) should not be deleted and should read " If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code."
R 338.563 Rule 63 (B) MPA is not aware of any specific training programs that cover all listed topics and believes this responsibility should lie with the wholesaler rather than the board.

408 Kalamazoo Plaza | Lansing, MI 48933 | ph (517) 484-1466 | fx (517) 484-4893 | MichiganPharmacists.org

R 338.587 Rule 87 (3) (vii) Remove "name of the manufacturer."
R 338.587 Rule 87 (4) (vii) Remove "name of the manufacturer."
R 338.587 Rule 87 (6) Subrule (2) should be included in this section.
R 338.588 Rule 88 (1) Consider keeping the current rule, "An automated device means a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription."
R 338.588 Rule 88 (h) MPA would like clarification if the location would need to be owned and operated by the pharmacy and who would be responsible for the device.
R 338.588 Rule 88 (4) Remove "unless the prescriber's office is affiliate with a hospital consisted with section 17760 of code, MCL 333.17760." This is not relevant to this section.
R 338.588 Rule 88 (5) after "licensed" add "and located."
R 338.588 Rule 88 (7)(a) after "pharmacy" add "or dispensing prescriber."
R 338.590 Rule 90 (11) after "prescriptions" add issued by an appropriate prescriber" and remove "of the attending physician."

If you have any questions please don't hesitate to contact me.

Thank you,
Brian Sapita
Government Affairs Manager
Phone: 517.377.0254
Email: Brian@MichiganPharmacists.org

Ditschman, Andria (LARA)

From: Watson, Neal <nwatson@nabp.pharmacy>
Sent: Thursday, October 03, 2019 10:56 AM
To: Ditschman, Andria (LARA)
Subject: RE: Public Comment Period Pharmacy Rules

Hi Andria,

I'm sorry for the delayed response.

Our comment is to mirror your license by exam rules to require the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) under your License by Endorsement.

R 338.513 Educational limited license; application and renewal; practices.
Rule 13. (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and MCL 333.17737, the applicant shall establish either of the following:
(a) That he or she is actively enrolled in, or is within 90 days of having graduated from, an approved educational program.
(b) That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the national association of boards of pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ .

R 338.521 Pharmacist licensure by examination.
Rule 21. (1) An applicant for licensure as a pharmacist by examination shall submit to the department a completed application on a form provided by the department with the requisite fee.
(2) In addition to meeting the requirements of section 16174 of the code, MCL 333.16174, an applicant for licensure shall satisfy all of the following requirements:
(a) Earned either of the following:
(i) A professional degree from a school of pharmacy accredited by the American council of pharmaceutical education or the Canadian council for accreditation of pharmacy programs.
(ii) A foreign pharmacy graduate examination committee certificate administered by the NABP.
(b) Successfully passed the MPJE and the NAPLEX.
(c) Completed an internship as set forth in R 338.515.
(3) An applicant's license shall be verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

R 338.523 Pharmacist license by endorsement; requirements.
Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.
(2) An applicant shall satisfy all of the following requirements:

(a) Establish that the he or she is currently licensed in another state and was initially licensed by examination in another state.
(b) Pass the MPJE as required under R 338.519.
(c) Have his or her license verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.
(d) Submit the MPJE examination score report and NABP licensure transfer report to the department.

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

Is this sufficient for comment?

Thank you,
Neal

Neal Watson, Member Liaison
847/391-4481

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | jbolin@nabp.pharmacy

From: Ditschman, Andria (LARA) <DitschmanA@michigan.gov>
Sent: Thursday, October 3, 2019 7:59 AM
To: Watson, Neal <nwatson@nabp.pharmacy>
Subject: RE: Public Comment Period Pharmacy Rules

Hi Neal,

I have not yet received your comments regarding the pharmacy rules. Just a reminder.

Andria M. Ditschman, JD
Senior Analyst
Boards and Committees Section
Bureau of Professional Licensing
Michigan Department of Licensing and Regulatory Affairs
611 W. Ottawa Street
P.O. Box 30004
Lansing, Michigan 48909

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

Testimony/Comments Received:

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

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

Rule Numbers	Commenter	Comment
Section (1)(a)	Eid/Ferris	Add "home of the aged" to the definition of "medical institution" as LARA has a Division of Adult Foster Care and Homes for the Aged. Provides inclusivity.
Section (3)	Baran/Ferris	Delete "inpatients" and replace with "patients of a medical institution." Do not delet "who is on the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(i)~~ **(j)** Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist ~~shall~~ **must** be available on an on-call basis. Only a limited number of medications that are packaged in units of use ~~shall~~ **must** be available. The medications ~~shall~~ **must** be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication ~~shall~~ **must** be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication ~~shall~~ **must** be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document ~~shall~~ **must** be obtained for each medication ~~united~~ **unit** removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon recommendation of an interdisciplinary ~~practitioners~~ **practitioners'** committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct

medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.

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

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

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

Board Response	(1)(a): The Board does not agree with the comment to add "home of the aged" to the definition of "medical institution," as the definition includes "health facility," which under Article 17 of the Public Health Code includes a home for the aged. (3): The Board agrees with the comments to not remove "who is on the premises."

Rule 338.501 Definitions.

Rule Numbers	Commenter	Comment
Section (1)(j)	Sapita/MPA	"Virtual manufacturer" is not defined in the statute and should be.
Section (1)(e)(4)	Milenkovich/Much Shelist	USP has indicated they intend to classify all flavorings of conventionally manufactured medications as nonsterile compounding. Fourteen state boards of pharmacy have language on their books excluding flavoring from the definition of compounding. The request is to implement a regulation excepting the safe administration of flavorings added to conventionally manufactured medications from the definition of compounding. The Board can achieve this by narrowing the use

		of flavoring agents to conventionally manufactured and commercially available liquid medications and by setting conditions to ensure safe administration of flavorings (ie favoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume).
Rules Committee Response	(1)(j): The Rules Committee made no recommendation on the comment as the comment was withdrawn. (1)(e)(4): The rules committee agrees with the comment to exclude flavoring as an exception to the compounding rule as long as there is no other product manipulation.	

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

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

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

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

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

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

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

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

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

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

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

(i) Owns either of the following:

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

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

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

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

(iv) At no time takes physical possession of or stores the drugs or devices.
(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.

Board Response	(1)(j): The comment was withdrawn by the commenter. (1)(e)(4): The Board agrees with the comment to exclude flavoring as an exception to the compounding rule as long as there is no other product manipulation.

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

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

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.
Rule 3. (1) Prescription drugs or devices that have been dispensed and have left the control of the pharmacist must not be returned or exchanged for resale.
(2) This rule does not apply to any of the following:
(a) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail, as provided in section 17766d of the code, MCL 333.17766d.
(b) A pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided in section 17775 of the code, MCL 333.17775.

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

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

Board Response	The Board agrees with the comment to add "(d) Drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock." The addition of this language will allow the return of drugs in 2 additional circumstances that are not currently in the rules, subject to any controlled substances exceptions or limitations.

Rule 338.505 Inspection of applicants and licensees.

Rule Numbers	Commenter	Comment
R 338.505	Baskerville	This draft rule mentions that the approved entity may enter any facility that is eligible for inspection "at reasonable times". The statement about the time needs to be more specific because "reasonable" is largely open to interpretation. Add 9:00 a.m.-5:00 p.m. after the phrase "reasonable times". It should read "…may enter between the reasonable times of 9:00 a.m. and 5:00 p.m., any building…"
Section (e)	Carlson/MHA	Modify to: (e) Research data. (f) Information gathered by a licensed health facility for quality improvement or professional practice review.
Rules Committee Response	The Rules Committee does not agree with the comment limiting the accessibility for inspections due to safety concerns. (1)(f): The Rules Committee agrees with the comment to add (f) above.	

R 338. 505 Inspection of applicants and licensees.

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

(1) The inspection must not extend to any of the following information:
(a) Financial data.
(b) Sales data other than shipment data.
(c) Pricing data.
(d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.
(e) Research data.
~~(f) Information gathered by a licensed health facility for quality improvement or professional practice review.~~
(2) An applicant or license holder shall permit and cooperate with the inspection.

Board Response	The Board does not agree with the comment to limit the accessibility for inspections due to safety concerns. (1)(f): The Board agrees with the comment to add (f) above that does not allow the department to access information gathered for quality improvement or professional practice review during an inspection as this information is not pertinent to an inspection to determine if an applicant possesses the qualifications and competence for the license being sought or to determine if the licensee is complying with the code and rules.
Department Response	(1)(f): The Department does not agree with adding the suggested language as it may be relied on by a pharmacy for a basis to refuse to comply with a Department investigative subpoena. Although Article 17 protects hospital peer review from disclosure in Department investigations, the Department is not aware of this privilege being extended to pharmacies within such facilities. Additionally, the statutory privilege provided to hospitals relates to only data tied to the reduction of mortality rate and improvement of patient care.

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

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

	(3): The rules committee agrees with the comment that the dates in this rule and the dates in the pharmacist CE rules must be consistent. No change to this rule is necessary.

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

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

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

(i) Understanding the types and venues of human trafficking in the United States.

(ii) Identifying victims of human trafficking in health care settings.

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

(iv) Resources for reporting the suspected victims of human trafficking.

(b) Acceptable providers or methods of training include any of the following:

(i) Training offered by a nationally recognized or state-recognized, health-related organization.

(ii) Training offered by, or in conjunction, with a state or federal agency.

(iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.

(iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer reviewed journal, health care journal, or professional or scientific journal.

(c) Acceptable modalities of training may include any of the following:

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

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

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

(b) A self-certification statement by an individual. The certification statement must include the individual's name and either of the following:

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

(ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer review journal, health care journal or professional or scientific journal, and date, volume, and issue of publication as applicable.

(3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning in January 1, 2020 and for initial licenses issued after November 13, 2022.

Board Response	The Board agrees with the comment to clarify that a limited licensee must meet the human trafficking training requirement. No change to this rule is necessary. A reference to R 338.511, which requires the training, is recommended in R 338.513. (3): The Board agrees with the comment that the dates in this rule and the dates in the pharmacist CE rules should be consistent.

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

Rule Numbers	Commenter	Comment
Section (1)(a) and (2)(a)	Sapita/MPA	Remove "90 days" and replace with "180 days."
Section (1)(a) and (2)(a)	Baskerville	The rule only allows renewal of a limited education license within 90 days after graduating from an approved educational program. Ninety days is not enough time because if a graduate does not pass the NAPLEX, they must wait 45 days to take the exam again. The window is tight, and it should be longer to accommodate more graduates. Modify 1a and 2a to 180 days instead of 90 days.
Section (3)	Sapita/MPA	Replace with "An educational limited licensee must engage in the practice of pharmacy under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist."
Section (4)	Roath/SpartanNash	In the context of the Proposed Rule 13, this subrule seems to require that an educational limited licensee (pharmacy intern) only practice under the direct personal supervision of a pharmacist licensed as a preceptor. Previously, this requirement only extended to pharmacy interns working towards the intern hours required to obtain their full pharmacist license. The language, as proposed, would create a barrier for pharmacy interns seeking to gain additional experience

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

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

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

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

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

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

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

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

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

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

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

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

Board Response	(1)(a) and (2)(a): The Board agrees with the comment to replace "90 days" with "180 days." (3)(4): The Board agrees with the comments that the rules should be clarified to indicate that a licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist. However, if the licensee wants to count the hours towards the required internship they must also be acting under a preceptor. The Board does not agree with the proposed language in either comment to (3) or (4) above. (6): The Board agrees with the comment to add the requirement of the human trafficking training.

Rule 338.515 Internship requirements.

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

R 338.515 Internship requirements.

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

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

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

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

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

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

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

Board Response	The Board did not evaluate the comments to this rule as both comments were withdrawn.

Rule 338.519 Examinations adoption; passing scores; reexamination.

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

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

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

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

R 338.519 Examinations adoption; passing scores; reexamination.

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

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

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

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

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

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

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

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

Board Response	The Board agrees with the comments to: • Modify (4) to "within 3 attempts" not 1 attempt. • Modify (7) and add (8) to require an applicant to take a pharmacy law course in an educational program or redo the program depending on which examination they have failed 5 times. • Delete the reference to the foreign pharmacy graduate equivalency examination certification program as a foreign graduate should be held to the same standard if they are failing the examinations. The Board does not agree with the other comments as they are too restrictive.

Rule 338.521 Pharmacist licensure by examination.

Rule Numbers	Commenter	Comment
Section (2)(i)	Carlson/MHA	Under the "Pharmacist licensure by examination" section, it is important to note that Canadian Council for Accreditation of Pharmacy Programs uses different criteria than the Accreditation Council for Pharmacy Education. Modify to: A professional degree from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education or the Canadian council for accreditation of pharmacy programs.
	Sapita/MPA	Remove "Canadian council for accreditation of pharmacy programs." The Canadian Healthcare System is significantly different than that of the United States and should be removed from the rules.
Rules Committee Response	(2)(i): The Rules Committee agrees with the comment to delete the reference to the Canadian Council for Accreditation of Pharmacy Programs as it is not equivalent to ACPE.	

R 338.521 Pharmacist licensure by examination.

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

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

(a) Earned either of the following:

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

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

(b) Successfully passed the MPJE and the NAPLEX.

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

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

Board Response	(2)(i): The Board agrees with the comment to delete the reference to the Canadian Council for Accreditation of

	Pharmacy Programs as it is not equivalent to ACPE.

Rule 338.523 Pharmacist license by endorsement; requirements.

Rule Numbers	Commenter	Comment
(2)(a)	Watson/NABP	Mirror the license by exam rules to require the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) under the License by Endorsement as follows: That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the national association of boards of pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ . AND: A foreign pharmacy graduate examination committee certificate administered by the NABP.
Rules Committee Response	(2)(a): The Rules Committee agrees with the suggested change to require passing the examination and meet the FPGEC requirements.	

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.

(2) An applicant shall satisfy all of the following requirements:

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

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

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

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

Board Response	(2)(a): The Board agrees with the suggested change to require passing the examination and obtaining the FPGEC

	certificate from NABP.

Rule 338.525 Relicensure of a pharmacist license; requirements.

Rule Numbers	Commenter	Comment
Section (1) and (2)	Eid/Ferris	Questions what happens to applications when the new CE requirements become effective and shouldn't the one-time trainings be required for relicensure?
Section (1)(f) and (g)	Sapita/MPA	Remove "or outside of Michigan."
Rules Committee Response	The Rules Committee agrees with the comment to clarify that relicensure will not be granted until the continuing education requirements are met, and that to meet relicensure an applicant must meet the one-time training requirements. (1)(f) and (g): The comment to remove " or outside of Michigan" is withdrawn.	

R 338.525 Relicensure of a pharmacist license; requirements.

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

(1) For a pharmacist who has let his or her license lapse and who is not currently licensed in another state:	**License lapsed 0-3 years**	**License lapsed more than 3 years, but less than 8 years**	**License lapsed 8 or more years**
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	**X**	**X**	**X**
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	**X**	**X**	**X**

(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		**X**	**X**
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	**X**	**X**	**X**
(e) Submit proof of having completed both a 1-time training in identifying victims of human trafficking as required in R 338.511 and a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.	**X**	**X**	**X**
(f) Pass MPJE: retake and pass the MPJE as provided in R 338.519.		**X**	**X**
(g) Practical experience: complete 200 hours of practical experience under the personal charge of a currently		**X**	

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

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

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

(4) For a pharmacist who has let his or her pharmacist license lapse, but who holds a current and valid pharmacist license in another state:	**License lapsed 0-3 Years**	**License lapsed more than 3 years, but less than 8 years**	**License lapsed 8 or more years**
(a) Application and fee: submit to the	**X**	**X**	**X**

department a completed application on a form provided by the department, with the requisite fee.			
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	**X**	**X**	**X**
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		**X**	**X**
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	**X**	**X**	**X**
(e) Submit proof of having completed both a 1-time training in identifying victims of human trafficking as required in R 338.511 and a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.	**X**	**X**	**X**
(f) Examination: retake and pass the MPJE as provided in R 338.519.		**X**	**X**

(g) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant holds or has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the applicant.	**X**	**X**	**X**

Board Response	The Board agrees with the comment to clarify that relicensure will not be granted until the continuing education requirements are met, and that to meet relicensure an applicant must meet the one-time training requirements. (1)(f) and (g): The comment to remove " or outside of Michigan" is withdrawn.

Rule 338.531 Pharmacy license; applications; requirements.

Rule Numbers	Commenter	Comment
Section (3)	Baran/Ferris	This should be modified to: (3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared, or dispensed, or prescriptions received, each address location shall obtain a separate license. This is to align with MCL 333.17722 and also require any location where prescriptions are dropped off for filling would need to be licensed.
	Sapita/MPA	MPA recommends the language mirrors R 338.477 "If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required."
Section (4)	Baran/Ferris	Add USP Chapter 797 to make it consistent with Rule 338.533(1).
	Kuhns/Portage Pharmacy	Delete "and 800".
	Roath/SpartanNash	The adoption of these reference standards in conjunction with the clause in (4)(b) seems to imply that the standards are only applicable to pharmacies providing compounding services, though this is not explicit. Additionally, some of the guidance in the standards extend to practices beyond

		compounding and it is unclear as to whether pharmacies operating under the purview of these standards would be required to comply with the full reference standard, or just the areas that apply to compounding practices. Additionally, recent comments at the NABP Annual meeting by a USP representative suggest that the USP's intent regarding general chapter 800 indicate that this guidance was intended to apply to compounding activities only. To provide additional clarification, we recommend that Rule 31, Subrule (4)(b) be modified to read: "A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule as they apply to compounding services as defined in Michigan law."
Section (4)	Sullivan/Michigan Surgical Hospital	Requests not adopting USP 797 and 800 and urges the Board to consider having MIOSHA adopt USP 800 as an occupational health standard so it can be equally applied to all professions.
Rules Committee Response	(3): The Rules Committee does not agree with modifying the language in (3) and more discussion is needed. (4): The Rules Committee members are split regarding the comment to delete USP 800 from the rule until it is published in the compendium. The Rules Committee does not agree with modifying the rules to clarify that USP 800 applies to pharmacies that do not handle compounding or other entities such as offices and clinics. As the Board does not have authority over MIOSHA it may not require it to adopt USP 800.	

R 338.531 Pharmacy license; applications; requirements.

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

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

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

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

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

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

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

(f) A completed self-inspection form.

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

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

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

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

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

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

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

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

Board Response	(3): The Board does not agree with the suggested comments as it believes the current language is appropriate. (4): The Board agrees with the comments to delete USP 800 from the rule until it is published in the compendium. The Board agrees with adding USP 797 for consistency. The Board does not agree with modifying the rules to clarify that USP 800 applies to pharmacies that do not handle compounding or other entities such as offices and clinics, although this comment is moot at this time as the Board is not recommending adoption until it is published in the compendium. (2)(g) and (i): As the Board agrees with the comments to R 338.532 and R 338.533 to delete the term "sterile" as the rules should regulate sterile and non-sterile compounding, for consistency, "sterile" will also be deleted from R 338.531.

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

Rule Numbers	Commenter	Comment

Section (1)	Kuhns/Portage Pharmacy	Modify as follows: (1) The board shall approve, under section 17748~~a~~ of the code, MCL 333.17748~~a~~, accrediting or inspection organizations ~~or inspection entities~~ for ~~pharmacies~~ entities that compound ~~sterile~~ pharmaceuticals according to standards adopted by reference in R 338.533. Add: (1)(a)"Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.
Section (3)	Eid/Ferris	How often must an inspection be submitted? Are the details of the inspection required to be shared with the state?
Rules Committee Response	(1): The Rules Committee does not agree with broadening the requirement of an inspection under MCL 333.17748a to more than pharmacies as this would require a change to the Public Health Code. The Rules Committee agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as both rules should regulate sterile and non-sterile compounding. (3): The Rules Committee agrees with the comment that the results of pharmacy inspections should be required to be shared with the Department but does not agree that the rule should include a set expiration date of a certain amount of years for accreditation approvals. The inspection entity should submit the length of their accreditation approvals with their application as an approval entity.	

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

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

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

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

(a) Requirements for accreditation or compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

(e) The length of accreditation.
(f) Agreement and plan to share results of inspections with the Department.
(4) If the board approves the petition, the approval is valid for 3 years from the date of approval. The organization may submit a petition that complies with subrule (3) of this rule to seek continuing approval.
(5) The board may rescind approval of an organization upon just cause. The rescission will not immediately affect the compliance of a pharmacy using the accreditation. Within 12 months of the rescission date or by the next licensure renewal date, whichever is later, the accreditation is void, and a pharmacy shall obtain accreditation or an inspection from an organization that satisfies subrule (1) of this rule.

Board Response	(1): The Board does not agree with broadening the requirement of an inspection under MCL 333.17748a to more than pharmacies as this would require a change to the Public Health Code. The Board agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as both rules should regulate sterile and non-sterile compounding. For consistency "sterile" will also be deleted from R 338.531. (3): The Board agrees with the comment that the results of pharmacy inspections should be required to be shared with the Department and does not agree that the rule should include a set expiration date of a certain amount of years for accreditation approvals. The inspection entity should submit the length of their accreditation approvals with their application as an approval entity.

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

Rule Numbers	Commenter	Comment
Section (1)	Popyk/Health Dimensions	Delete adoption of USP 795, 797, and 800.
Section (1) – (10)	Kuhns/Portage Pharmacy	Modify as follows: R 338.533 ~~Sterile~~ Compounding standards and requirements; ~~outsourcing facilities; requirements~~. Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP) Chapters 795 and 797., published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. ~~This includes, but is not limited to, USP Chapters 795, 797, and 800.~~

		(2) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP) Chapter 800 for entities engaged in compounding, preparing, or otherwise manipulating antineoplastic drugs. **(a)** "Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities. **(b)** "Antineoplastic drugs" means substances identified as antineoplastic drugs by the National Institute of Occupational Safety and Health (NIOSH). **(3)** The standards adopted by reference in subrule (1) and (2) of this rule are available at cost at http://www.usp.org/compounding, or at cost from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909. **(4)** A pharmacy, physician private office, dental private office, podiatric private office, veterinarian private office, infusion center, surgical outpatient facility, hospital, health facility, or outsourcing facility that provides ~~sterile~~ compounding services shall comply with all current standards adopted in subrule (1) and (2) of this rule. **(5)** An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes ~~sterile~~ compounded pharmaceuticals in this state ~~must~~ shall be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state. **(6)** ~~An outsourcing facility must undergo an inspection by the board, or a third party recognized by the board if the outsourcing facility is registered with the FDA but has not received an FDA inspection as an outsourcing facility. Third party inspection providers approved by the board must be posted on the department's website~~. **(7)** A licensed outsourcing facility shall submit to the board a copy of the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form. **(8)** An outsourcing facility shall do all of the following: **(a)** Compound drugs by or under the supervision of a licensed pharmacist. **(b)** Compound drugs pursuant to current good manufacturing practices for finished

		pharmaceuticals set forth in 21 C.F.R. sections 211.1 to 211.208 (1978). **(c)** Ensure that a pharmacist or pharmacists who conducts or oversees ~~sterile~~ compounding at an outsourcing facility is proficient in the practice of ~~sterile~~ compounding and has acquired the education, training, and experience to maintain that proficiency by doing any of the following: **(i)** Participating in seminars. **(ii)** Studying appropriate literature. **(iii)** Consulting with colleagues. **(iv)** Being certified by a compounding certification program approved by the board. **(d)** Label compounded drugs with all of the following: **(i)** Required drug and ingredient information. **(ii)** Facility identification. **(iii)** The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale." **(e)** Ensure that bulk drug substances used for ~~sterile~~ compounding meet specified FDA criteria. **(9)** An outsourcing facility may compound drugs that appear on an FDA shortage list, if the bulk drug substances used to compound the drugs comply with the criteria specified in this rule. **(10)** An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need. The term "Secretary" means the Secretary of Health and Human Services of the United States.
Section (7)(c)(iv)	Clark/bps	Bps encourages the BOP to recognize bps Board Certification in Compounded Sterile Preparations as meeting the standards in (c)(iv) as " a compounding certification program approved by the board."
Section (7)(d)(i), (ii), and (iii)	Baran/Ferris	Modify to: "(d) label compounded drugs in compliance with the Federal Food, Drug, and Cosmetic Act 503B(10) and rule 338.582."

		The label must include the requirements of both the state and federal law. This would be easier to quote the federal law at **(7)(d)** instead of listing all of the following. "`(10) Labeling of drugs.-- ``(A) Label.--The label of the drug includes-- ``(i) the statement `This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug; ``(ii) the name, address, and phone number of the applicable outsourcing facility; and ``(iii) with respect to the drug-- ``(I) the lot or batch number; ``(II) the established name of the drug; ``(III) the dosage form and strength; ``(IV) the statement of quantity or volume, as appropriate; ``(V) the date that the drug was compounded; ``(VI) the expiration date; ``(VII) storage and handling instructions; ``(VIII) the National Drug Code number, if available; ``(IX) the statement `Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement `Office Use Only'; and ``(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient."

		Also, the label needs to meet the requirements in Rule 338.582, and it would be easier to state the rule number and not all the details in the rule.
Section (7)(a)	Carlson/MHA	"Supervision" is not defined in the Code or the rules. The Code and rules generally use "personal charge" in reference to needing the immediate presence of a pharmacist. Modify supervision to personal charge.
Rules Committee Response	(1): The Rules Committee members are split regarding whether to delete references to USP chapters in the rules as USP is adopted in the Code or to specifically refer to USP chapters 795, 797, and 825, and if the rules should reference the specific date of the published compendium. The consensus is to continue discussion with the full Board. The Rules Committee suggested referencing the statutory requirement of complying with USP instead of listing each chapter. (1) to (10): The Rules Committee agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as both rules should regulate sterile and non-sterile compounding. (4): The Rules Committee does not agree with modifying the rules to clarify that USP applies to entities other than pharmacies, including private physician offices, dental offices, podiatric offices, veterinarian offices, infusion centers, surgical outpatient facilities, hospitals, and health facilities. The Rules Committee agrees with further expanding the term "distributes" to "dispenses, provides, distributes, or otherwise furnishes." (5): The Rules Committee is split on whether to limit inspections to the FDA for outsourcing facilities that deal with compounded pharmaceuticals in Michigan. (7)(a): The Rules Committee does not agree with changing supervision to personal charge. The pharmacist must be on site. 7(c)(iv): The Rules Committee does not agree with listing the entities that provide accreditation in the rules because adding entities or taking them off of the list would require modifying the rules. 7(d)(i), (ii), and (iii): The Rules Committee recommends adding the proposed language for clarity, and also reference R 338.582 for patient specific drugs. (10): The Rules Committee agrees with adding the language to (10) if the language is consistent with Federal law and is not already in the definition.	

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

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

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

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

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

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

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

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

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

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

(iv) Being certified by a compounding certification program approved by the board.

(d) Label compounded drugs with all of the following and label compounded drugs that are patient specific with all of the following and consistent with the requirements in R 338.582:

(i) Required drug and ingredient information.

(ii) Facility identification.
(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."
(e) Ensure that bulk drug substances used for ~~sterile~~ compounding meet specified FDA criteria.
(7) 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.
(8) An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the United States Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need.

Board Response	(1): The Board does not agree with the comment to delete references to USP chapters in the rules. (1) to (10): The Board agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as the rules should regulate sterile and non-sterile compounding. For consistency "sterile" will also be deleted from R 338.531. (4): The Board does not agree with modifying the rules to clarify that USP applies to entities other than pharmacies, including private physician offices, dental offices, podiatric offices, veterinarian offices, infusion centers, surgical outpatient facilities, hospitals, and health facilities. The Board agrees with further expanding the term "distributes" to "dispenses, provides, distributes, or otherwise furnishes." (5): The Board agrees with the comment that only the FDA should inspect an outsourcing facility that handles compounded pharmaceuticals in this state which is registered as an outsourcing facility by the FDA. (6)(a): The Board does not agree with changing supervision to personal charge. The pharmacist must be on site. (6)(c)(iv): The Board does not agree with listing the entities that provide accreditation in the rules because adding entities or taking them off of the list would require modifying the rules. (6)(d)(i), (ii), and (iii): The Board accepts the comment to add the proposed language for clarity, and also reference R 338.582 for patient specific drugs. New: The Board agrees with adding the language "An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need" if consistent with Federal law and is not already included in the definition of an outsourcing facility.

Rule 338.534 Inspections.

Rule Numbers	Commenter	Comment
Section (5)	Carlson/MHA	Under the "Inspections of applicants and licensees" section, the MHA feels the inspection should

		also exclude data gathered by the licensed health facility for quality improvement or professional practice review purposes. The collection of quality improvement data enables providers to work to improve patient safety and reduce the incidence of adverse events. This data could be incorrectly interpreted, which may deter providers from collecting data for quality improvement purposes. Professional practice evaluation is the process by which a health facility, using its own medical staff, performs a peer review of a privileged practitioner's professional practice for performance improvement and to ensure safe and high-quality patient care. The data should be left out of the inspection to ensure honest research and responses, which will ultimately lead to improved patient safety and quality. Michigan hospitals are committed to transparency and share quality of care data to state residents at verifymicare.org. Also, add the Joint Commission to (4).
Section (4)	Sapita/MPA	Remove "the NABP-VPP" replace with "a board approved accrediting organization."
Rules Committee Response	(4): The Rules Committee agrees with the comment to replace the existing language with "a board approved accrediting organization" instead of listing each organization. (5): The Rules Committee agrees with Carlson/MHA's comments and recommends adding the following language, (5) "The inspection shall not extend to information gathered by a licensed health facility for quality improvement or professional practice review."	

R 338.534 Inspections.

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

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

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

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

(i) The department.

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

(iii) An accrediting organization according to R 338.532.

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

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

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

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

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

Board Response	(4): The Board agrees with the comment to replace the existing language with "a board approved accrediting organization" instead of listing each organization. (5): The Board agrees with Carlson/MHA's comments and recommends adding the following language, (5) "The inspection shall not extend to information gathered by a licensed health facility for quality improvement or professional practice review."
Department Response	(5): The Department does not agree with adding the suggested language as it may be relied on by a pharmacy for a basis to refuse to comply with a Department investigative subpoena. Although Article 17 protects hospital peer review from disclosure in Department investigations, the Department is not aware of this privilege being extended to pharmacies within such facilities. Additionally, the statutory privilege provided to hospitals relates to only data tied to the reduction of mortality rate and improvement of patient care.

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

Rule Numbers	Commenter	Comment
Section (1)	Kuhns/Portage Pharmacy	Add "or outsourcing facility" to (1): A sterile compounding pharmacy or outsourcing facility.
Section (3)		Add the following: (3) An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-10).

Rules Committee Response	(1) and (3): The Rules Committee agrees with the suggested changes to provisions (1) and (3).

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

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

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

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

(4) An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-7).

Board Response	(1) and (3): The Board agrees with the changes to provisions (1) and (3).

Rule 338.536 Housing of a pharmacy.

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	The 150 square feet requirement has been in the rule for over 30 years. Given the increase in technology and the number of drugs requiring an increase in space this minimum should be at least 250 square feet for any new licenses issued. 250 square feet is used by a couple of the great lake states.
	Baskerville	This rule states that there should be not less than 10 feet of free counterspace, but it does not consider the amount of technology that a pharmacy utilizes or the technicians. A minimum of 10 feet is too small when you account for computers, printers, fax machines, and separate workspaces for the technicians. Add: not less than 16 feet of free workspace.
Section (3)	Baran	Add exception here for restroom breaks and assisting patients in the over the counter purchases.
Rules Committee	(2) and (3): The Rules Committee does not agree with the suggested modifications to (2) or (3) as the current space	

Response	requirement is appropriate and the pharmacist is still on the premises while in the restroom.

R 338.536 Housing of a pharmacy.

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

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

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

Board Response	(2) and (3): The Board does not agree with the suggested modifications to (2) or (3) as the current space requirement is appropriate and the pharmacist is still on the premises while in the restroom.

Rule 338.537 Professional and technical equipment and supplies.

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

R 338.537 Professional and technical equipment and supplies.

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

(a) Drawers, shelves, and storage cabinets.

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

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

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

Board Response	(2): The Board does not agree with the comment to add requirements on a freezer as the pharmacist must use their professional judgment and this is part of professional responsibility.

Rule 338.538 Closing pharmacy.

Rule Numbers	Commenter	Comment
Section (d)	Baran/Ferris	Change this to 14 days to coincide with federal requirements. Should there be a provision regarding the result when a pharmacist passes away. What happens to the pharmacy license? Is a pharmacy license renewal the same process as the initial process?
Rules Committee Response	(1)(d): The Rules Committee does not agree with changing 15 days to 14 days as this requirement is necessary when the pharmacy is registered with the DEA. One day does not have any effect on the public's safety. The Rules Committee does not agree with the comment to add a rule regarding the death of a PIC as there is already a rule regarding changes to a PIC.	

R 338.538 Closing pharmacy.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

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

Board Response	(1)(d): The Board does not agree with changing 15 days to 14 days as this requirement is necessary when the pharmacy is registered with the DEA. One day does not have any effect on the public's safety. The Board does not agree with the comment to add a rule regarding the death of a PIC as there is already a rule regarding changes to a PIC.

Rule 338.551 Manufacturer license; application.

Rule Numbers	Commenter	Comment
	Sapita/MPA	MPA believes that R 338.493a(3), proposed R 338.561(b), should not be deleted and should read " If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code."
Rules Committee Response	The Rules Committee agrees that prior R 338.493a(3), proposed R 338.561(b), should not be deleted, but should be moved to R 338.551 as it applies to a manufacturer license.	

R 338.551 Manufacturer license; application.

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

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

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

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

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

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

(e) A completed compliance checklist for manufacturers.

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

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

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

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

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

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

Board Response	The Board agrees that prior R 338.493a(3), proposed R 338.561(b), should not be deleted entirely from the rules. However, the Board recommends moving R 338.561(b)(b) to R 338.551 as it applies to a manufacturer license.

Rule 338.561 Pharmacy as wholesale distributor; licensure.

Rule Numbers	Commenter	Comment
Section (b)	Baran/Ferris	Need to delete (b) entirely as (b) is in violation of 333.17748a(7) and the Drug Quality and Security Act section 503A, a pharmacy may only compound a drug for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner. A pharmacy may not compound drugs for resale.
	Baskerville	This draft rule does not consider the federal law that states that a pharmacy cannot sell another pharmacy a compounded product. Delete (b).
Rules Committee Response	The Rules Committee does not agree with deleting (b) from the rules, but instead recommends moving (b) to R 338.551 as it applies to a manufacturer license.	

R 338.561 Pharmacy as wholesale distributor; licensure.

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

~~(a) Distributes~~ distributes more than 5% of the total dosage units of prescription drugs dispensed during any consecutive 12-month period, except in the following circumstances:

(a) The distribution of a drug a drug among hospitals or other health care entities which are under common control.

(b) Intracompany distribution of any drug between members of an affiliate, defined pursuant to the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC section 360eee(1), or within a manufacturer.

(c) Distribution of a drug by a charitable organization to a nonprofit affiliate of the organization, defined pursuant to the Federal Food, Drug, and Cosmetic Act of 2016, 21 USC section 360eee(1).

(d) Distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act.

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

Board Response	The Board does not agree with deleting (b) from the rules, but instead recommends moving (b) to R 338.551 as it applies to a manufacturer license. The Board also recommends modifying (a) as it is inconsistent with the Drug Quality and Security Act.

Rule 338.563 Wholesale distributor; application for licensure; requirements.

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

R 338.563 Wholesale distributor; application for licensure; requirements.

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

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

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

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

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

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

(e) A completed compliance checklist.

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

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

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

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

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

(1) A high school diploma.

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

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

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

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

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

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

(3) Knowledge and understanding of quality control systems.

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

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

(C) Experience equal to either of the following:

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

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

Board Response	The Board does not agree with the comments to modify the term "training program" or the requirements of a "training program" there is no requirement in the rule that the program be taught by a Board approved program or an educational institution, nor is the training program required to be taught by any specific entity. The Board believes the rule requires the "appropriate education and experience" for a facility manager, which is what is required by the Code.

Rule 338.582 Prescription drug labeling and dispensing.

Rule Numbers	Commenter	Comment
Section (3)	Baran/Ferris	Need to delete "**or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products**" from the rule. The rule was created before computer software was standard practice in pharmacy over 30 years ago. This terminology is no longer used on prescription labels because computers made it obsolete.
Section (3)	Kurzman/NACDS	Delete (3) for the following reasons: Under R 338.582 (2) and (3), the Board proposed rule changes that address labeling requirements when a brand vs. generic drug is dispensed. Language under subrule (2)(g) and (i) specifies that prescription labels must include the medication name and the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label". Notably, the proposed language further specifies under subrule (3) that when "a drug is dispensed that is not the brand prescribed… the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products." However, if the if the prescriber indicates "do not label"… [the] subrule does not apply…" We are concerned that altogether, the language in subrule (2)(g) and (i) and in subrule (3) is duplicative and may lead to confusion. To simplify and clarify this issue, we recommend that

		subrule (3) be stricken entirely as that provision is redundant to the requirements outlined in subrule (2)(g) and (i).
	Eid/Ferris	Although being worked on within the Pharmacy Technician specific rules, consider the following for both this section and the Pharmacy Technician rule set. Tech-check-tech, or as some states are now calling it "accuracy checking" or "technician product verifiction" has been successfully and safely practiced in some states for decades. There are approximately 20 studies to date on the topic in various settings including community based and health systems. **Adams et al** reviewed and demonstrated safety data, including that results of 11 studies published since 1978 indicate that technicians' accuracy in performing final dispensing checks is very comparable to pharmacists' accuracy (mean ± S.D., **99.6%** ± 0.55% versus **99.3%** ± 0.68%, respectively. **Frost et al** also reviews data in the community setting and also showed that in 2 studies that reported accuracy rates, pharmacy technicians performed at least as accurately as pharmacists (**99.445** vs **99.73%,** P = .484; **99.95** vs **99.74**, P < .05). In addition, there are multiple pilot and research programs in states such as Wisconsin, Tennessee, Iowa, South Dakota, and more which have been studying the workflow and outcomes of implementing these models. I encourage the board and other stakeholders to move forward on this as it will only help to improve patient care initiatives and allow for pharmacists to spend more time with patients as demonstrated by **Andreski et al.** I'd also encourage the board to refer to **Adams** for deliberations of the Idaho regulatory board on advancing technician practice, which an example from.
Rules Committee Response	(3): The Rules Committee agrees with the comment to delete "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products" from the rule but does not agree with deleting the rule in its entirety as the use of generic needs to be disclosed if being used. I n response to the Eid comment, the authority for a pharmacy technician to provide product verification is included in the proposed pharmacy technician rules so will not be addressed in these rules.	

R 338.582 Prescription drug labeling and dispensing.

Rule 82. (1) All labeling of prescription drugs must comply with the requirements of the code and the Federal Food, Drug, and Cosmetic Act of 2016, 21 U.S.C. sections 351 to 399f.

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

(a) Pharmacy name and address.

(b) Prescription number.
(c) Patient's name.
(d) Date the prescription was most recently dispensed.
(e) Prescriber's name.
(f) Directions for use.
(g) The name of the medication and the strength, unless the prescriber indicates "do not label."
(h) The quantity dispensed, if applicable.
(i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."
(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed ~~or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products~~. This subrule does not apply if the prescriber indicates "do not label."
(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed must be noted on the prescription.
(5) This rule does not apply to pharmacy services provided in a medical institution.

Board Response	(a): Typographical error – capitalize name of Act. (3): The Board agrees with the comment to delete "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products" from the rule but does not agree with deleting the rule in its entirety as the use of generic needs to be disclosed if being used. The authority for a pharmacy technician to provide product verification is included in the proposed pharmacy technician rules.

Rule 338.584 Noncontrolled prescriptions.

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

Response	"noncontrolled" would therefore be redundant.

R 338.584 Noncontrolled prescriptions.

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

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

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

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

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

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

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

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

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

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

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

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

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

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

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

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

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

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

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

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

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

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

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

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

Board Response	The Board does not agree with the comment as "noncontrolled" is used in the heading and adding "noncontrolled" would, therefore, be redundant. (5)(a): Typographical error. Capitalize federal Act.

Rule 338.585 Customized patient medication package.

Rule Numbers	Commenter	Comment
Section (b)	Baran/Ferris	Change the first sentence to: "A CPMP must be accompanied by any mandated patient information required under federal law."

		This would cover any medication guides required.
Rules Committee Response	The Rules Committee agrees with the comment.	

R 338.585 Customized patient medication package.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) The drug products require special packaging.

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

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

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

(i) The name and address of the patient.

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

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

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

(v) Any special labeling instructions.

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

Board Response	The Board agrees with the comment.

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

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	Delete (2) entirely as this method is outdated by the use of computers. This part is more than 40 years old with no one using this process today.
Section (3)(vii)	Sapita/MPA	Remove “name of the manufacturer.”

and (4)(vii)		
Section (6)	Sapita/MPA	Subrule (2) should be included in this section.
Rules Committee Response	(2): The Rules Committee does not agree with the comment as the manual method may be used in a natural disaster. (3)(viii) and (4)(viii): The comment was withdrawn. (6): Subrule will be added back in as its deletion was a typographical error.	

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

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

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

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

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

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

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

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

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration (DEA) number, if appropriate.

(v) The number of refills authorized.

(vi) The "dispense as written" instructions, if indicated.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

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

(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.

(d) The information required by subdivision (b) of this subrule must be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.

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

(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal DEA number, if appropriate.

(v) The number of refills authorized.

(vi) Whether the drug must be dispensed as written.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

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

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

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

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

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

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

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

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

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

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

Board Response	(2): The Board does not agree with the comment as the manual method may be used in a natural disaster. (3)(viii) and (4)(viii): The comment was withdrawn. (6): Subrule will be added back in as its deletion was a typographical error.

Rule 338.588 Automated devices.

Rule Numbers	Commenter	Comment
Section (1)	Sapita/MPA	Consider keeping the current rule, "An automated device means a device designed for the specific

		purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription."
(1)(h)		MPA would like clarification if the location would need to be owned and operated by the pharmacy and who would be responsible for the device.
Section (2)	Roath/SpartanNash	Statutory changes that have occurred since the original rules regarding the use of automated devices in healthcare settings, as well as the addition of Subrule (2)(h) in these proposed rules, creates the potential for automated devices to be used in locations outside a pharmacy but at the same physical address of the pharmacy. However, this is currently limited only to hospital settings. Given that hospital pharmacies do not have any differentiation in license classification and, in some circumstances, have the ability to operate as outpatient facilities, this creates an environment where certain outpatient pharmacies are able to use these devices in capacities that are denied to pharmacies in the community practice setting. To address this discrepancy, we recommend that Rule 88, Subrule (2)(a) be modified to read "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy."
Section (3)	Baran/Ferris	Add this language following the first sentence in (3) "*If the automated device contains controlled substances, the pharmacy must obtain an additional controlled substance license for the automated device as well as a DEA registration for the device.*
	Roath/SpartanNash	The current definition "automated device" in the Michigan Public Health Code and in the rules as proposed encompasses several devices that may be used in workflow for tasks other than the delivery of a medication to patient or other healthcare provider (e.g., counting machines and packaging devices operated by pharmacy staff as part of the dispensing process). We feel that to register each of these devices with the department goes beyond the intent of the Board and the Department and will cause devices that do not require department oversight to be erroneously registered with the Department. To correct this, we recommend that Rule 88, Subrule (3) be modified to read: "A pharmacy that operates an automated device under this section to deliver a drug or device directly to a patient or other healthcare provider shall notify the department of the automated device's location on a form provided by the department …"
Section (4)	Sapita/MPA	Remove "unless the prescriber's office is affiliate with a hospital consisted with section 17760 of

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

R 338.588 Automated devices.

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

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

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

(b) A hospital.

(c) A county medical care facility.

(d) A hospice.

(e) A nursing home.

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

(g) An office of a dispensing prescriber.

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

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

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

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

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

(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the dispensing prescriber for review by an agent of the board. This documentation must include at least all of the following information:

(i) Manufacturer name and model.

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

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

(A) Accuracy.
(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.
(F) Emergency procedures.
(G) Medication security.
(H) Quality assurance.

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

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

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

(i) Name and address of the pharmacy responsible for the operation of the automated device.
(ii) Name and address of the facility where the automated device is located.
(iii) Manufacturer name and model number.
(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.
(v) Policy and procedures for system operation that address at a minimum all of the following:
(A) Accuracy.
(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.

(F) Emergency procedures.
(G) Medication security.
(H) Quality assurance.
(I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.
(6) An automated device that is operated at a location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, must comply with section 17760 of the code, MCL 333.17760.
(7) Records and electronic data kept by automated devices must meet all of the following requirements:
(a) All events involving access to the contents of the automated devices must be recorded electronically.
(b) Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:
(i) The unique identifier of the automated device accessed.
(ii) Identification of the individual accessing the automated device.
(iii) The type of transaction.
(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.
(v) The name of the patient for whom the drug was ordered.
(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.
(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:
(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(j).
(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).
(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.
(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours
(e) The automated device is located in a dispensing prescriber's office.

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

Board Response	(1): The Board does not agree with the comment to change the definition of "automated device" as the definition of automated device is from the Code. (2): The Board agrees with the comment to add the language "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy." (3): The Board does not agree with the comment from Baran as this is already addressed in the controlled substances rules but does agree with the comment from Roath as this is current practice with a change of the term "patient" to "ultimate user." (4): The Board does not agree with the comment as the purpose of the provision is to state when a pharmacy can own a device at a dispensing prescriber's office. A reference to (2)(h) should be added here. (5): The Board agrees with the comment to delete the reference to R 338.3154. The comment from MPA is withdrawn. (7): The Board agrees with the comments to provision (7).

Rule 338.589 Professional responsibility; "caregiver" defined.

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

R 338.589 Professional responsibility; "caregiver" defined.

Rule 89. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and

devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code, MCL 333.17748, or from other lawful channels of distribution.

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

(a) The prescription appears to be improperly written.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Board Response	(4)(d): The Board does not agree with the comment to add a requirement not currently required by the Code. (5): The Board does not agree with the comment that there is no longer an exception in R 338.486. However, as there are multiple exceptions in this rule the reference to subsection (3) will be deleted.

Rule 338.590 Hospice emergency drug box.

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

R 338.590 Hospice emergency drug box.

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

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

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

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

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

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

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

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

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

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

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

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

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

(f) The number of the drug box.

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

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

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

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

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

(a) The number of the box.

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

(c) The date the box is released to the hospice.

(d) The name and signature of the pharmacist who releases the box to the hospice.

(e) The expiration date assigned.

(f) The date the box is returned to the pharmacy for restocking.

(g) The name and signature of the pharmacist who received the box for restocking.

(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the ~~attending physician~~ appropriate prescriber or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed from the hospice drug box on the back of the prescriptions. The prescriptions must be filed in the same manner as other prescriptions are maintained at the pharmacy.

Board Response	(11): The Board agrees with the comment to update the language.