MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
NOVEMBER 15, 2019

The Michigan Board of Pharmacy Rules Committee Work Group, met on November 15, 2019, at 611 West Ottawa Street, Upper Level Conference Center Room 5, Lansing, Michigan 48933.

CALL TO ORDER

Andria Ditschman called the meeting to order at 1:00 p.m.

ATTENDANCE

Members Present: Kathleen Pawlicki, MS, FASHP
James Stevenson, PharmD
Maria Young, R.Ph.

Members Absent: Charles Mollien, PharmD, JD

Staff Present: Andria Ditschman, Analyst, Boards and Committees Section
Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Rose Baran - Self
Michael E. Collins, R.Ph. – Healthway Compounding Pharmacy
Amy Drumm – Michigan Retailers Association
Marla Ekola - Michigan Health & Hospital Association – McLaren
Olivia Farhadi – Self
Paige Fults - Michigan Health & Hospital Association
Farah Jalloul – Michigan Pharmacists Association
Justin Kuhns – Portage Pharmacy
Joel Kurzman – National Association of Chain Drug Stores
Bradley McCloskey – University Compounding Pharmacy
Jonathan McLachlan – AllianceRx Walgreens Prime
Chad Mutson – Professional Compounding Centers of America
Eric Roath – Spartan Nash

Ahed J. Salamen – Clark Professional Pharmacy
Patrice Shook, C.Ph.T. – Pharmacy Solutions
Larry Wagenknecht – Michigan Pharmacists Association

WELCOME

Ditschman stated that the public hearing for the Pharmacy General Rules and Continuing Education (CE) Rules was held on October 4, 2019. She indicated that only comments received from the public hearing can be discussed. The Pharmacy Technician Rules have not yet gone to public hearing so they are open to any comment.

RULES DISCUSSION

Pharmacy Technician (A copy of the draft rules, revised pursuant to the meeting discussion, is attached)

Ditschman highlighted significant changes that were made within the draft after the last Rules Committee Work Group meeting.

R 338.3653 Licensure by endorsement.

Subrule (2)(c): Wagenknecht stated that he does not agree with allowing licensure based on licensure in another state, as the requirements may not be equivalent to the requirements in Michigan.

Pawlicki agreed with not recognizing licensure in Michigan based on another state's license.

Ditschman asked what the Rules Committee would like to see from an applicant when applying by endorsement.

Pawlicki stated that they should have to meet the same requirements as a new pharmacy technician.

Stevenson stated that subrule (2)(d) requires passage of a pharmacy technician examination.

Wagenknecht stated that subrule (2)(d) covers his concerns and therefore he no longer has concerns with subrule (2)(c).

R 338.3654 Examination requirements; passing score; application process.

Kurzman stated that meeting accreditation standards is burdensome on employer-based training programs.

Drumm stated that there is no evidence showing that accreditation improves the quality of work of the pharmacy technician.

Pawlicki stated that setting minimum consistent standards for training and an examination needed to be established. She does not want to modify the requirement for accreditation.

Stevenson agreed with Pawlicki. Setting a standard provides the Board a guideline when approving programs.

Pawlicki stated that there are many ways to design a program that are not burdensome. The Board should not be responsible for setting that standard.

R 338.3655 Approved pharmacy technician programs.

Ditschman gave an overview of some of the changes made to the rule.

Pawlicki asked why the Accreditation Council for Pharmacy Education (ACPE) was removed.

Stevenson stated that the ACPE is accredited by the U.S. Department of Education, so it is covered by the new language that references the Department of Education.

Ditschman stated that the Board approves programs and examinations. A student in a board approved program is allowed to work and be trained at the same time. Therefore, the examination should be tied to the program. If a training program is accredited, the examination that is tied to the program must also be acceptable to the accreditation entity. Employer-based training program requirements are not set in statute. However, the statute includes the subject matter that the examination must include.

Pawlicki asked if employer-based training programs need to be accredited. Ditschman stated that based on the Rules Committee's direction, the proposed rules require all employer-based training programs to be accredited by an entity that is recognized by the U.S. Department of Education.

Jalloul stated that the Pharmacy Technician Certification Board (PTCB) will be asking for training to be through a PTCB recognized program and wondered if that will be consistent with the proposed rules.

Wagenknecht stated that it wouldn't be a problem as it wouldn't be a Board approved employer-based training program.

Subrule (5): Baran requested the wording be changed to read "A student in the board…." Ditschman stated that wording is similar to the statute.

Roath asked what will be used to audit individuals in employer-based training programs so that they aren't staying in the program forever. Ditschman stated that she is not aware of an audit on the number of years someone is in an employer-based training program.

Subrule (4): Shook asked if two years was too restrictive.

Jalloul stated that the individual could apply for a temporary license at that time.

Pawlicki stated that two years was lenient.

Subrule (2): Wagenknecht suggested removing "or pharmacy."

The Rules Committee agreed to the suggested change.

R 338.3657 Relicensure requirements for pharmacy technicians.

Ditschman stated no changes have been made to this rule since the last Rules Committee Work Group meeting.

Subrule (2)(d): Jalloul stated that the pharmacy technician should provide proof of continuing education, the same as pharmacists are required to do, even when actively licensed in another state at the time of application for relicensure, when lapsed from 0-3 years.

Ditschman confirmed that pharmacists are required to provide proof of continuing education in the above instance.

The Rules Committee agreed to add this language for consistency. Therefore, a check mark will be added to the appropriate box under subrule (2)(d).

R 338.3660 English proficiency.

Ditschman stated that the language has been simplified. She stated that the Department is currently working on language for English proficiency to apply across all of the health professions.

Wagenknecht asked if English proficiency affected relicensure. Ditschman stated that an applicant must either meet the requirement at initial licensure or at first renewal after the rule is promulgated. It could be required at relicensure if it was not met at the initial licensure and there was not renewal before the license lapsed.

R 338.3661 License renewals; continuing education requirements.

Ditschman stated that no substantive changes had been made to the rule.

Ekola asked if this rule followed in line with pharmacists. Ditschman stated that the rule is the similar. The primary difference would be in the number of hours required.

Subrule (1)(ii): Wagenknecht asked if requiring clinical applications and drug interventions in the pain and symptom course was too specific. ACPE provides continuing education that is specific to what pharmacy technicians actually do.

Young stated that both could be removed.

Stevenson suggested only removing "drug interventions."

Pawlicki agreed with Stevenson.

Jalloul asked about removing "clinical applications."

The Rules Committee stated that "clinical applications" were needed and only "drug interventions" should be removed.

Baran asked for clarification of the renewal cycle. Ditschman explained the cycle.

R 338.3662 Format of acceptable continuing education for licensees.

Subrule (a): Ditschman stated that she added pharmacy technician educational program to (a) of the rule.

Jalloul asked if the pharmacist template was used. Ditschman stated it was used and changed to be applicable to pharmacy technicians.

Fults asked if human trafficking was included. Ditschman confirmed that the human trafficking requirement is required at renewal unless it was met with the initial license.

Subrule (b): Baran asked what was meant by postgraduate and suggested it be removed as it does not apply to pharmacy technicians.

Ekola asked where a pharmacy technician would obtain the credit. How does this rule apply?

Ditschman will delete "postgraduate."

Subrule (a): Wagenknecht stated that just because the school is ACPE accredited does not mean that the program offering continuing education at the school is ACPE accredited.

Jalloul agreed. The program would need to be accredited separately from the school in order to provide ACPE accredited continuing education.

Ditschman asked if changing “school” to “educational program” or “program” would correct the issue. Ditschman will be sure that the language is consistent with the Pharmacist Continuing Education rules.

The Rules Committee agreed to replacing “school” with “educational program” or “program.”

Ditschman asked if the pharmacy technician educational program in bullet point 2 should be removed.

Stevenson stated that the rule requires additional education outside of the program.

Wagenknecht stated that additional education is covered under subrule (b).

Ditschman stated that subrule (a) allows for the listed entities to approve and offer continuing education that is automatically accepted by the Board. The Rules Committee didn’t want a licensee to be able to meet their continuing education requirements by retaking the employer-based training program examination.

Stevenson stated that a pharmacy technician can use education from a pharmacy program as continuing education.

Ditschman stated that statute allows the Board to decide whether the program can be used as continuing education.

The Rules Committee would like the second bullet point removed and the wording in the first bullet point to read “educational program” instead of “school.”

R 338.3663 Continuing education standards for approval.

Ditschman pointed out the correction made within the rule.

Subrule (5)(d): Wagenknecht stated that a change to a speaker less than 70 days before the program is offered does not seem to be an emergency.

Ditschman clarified that this was for emergency needs, such as a change in speaker, less than the required 70 days needed for approval, so it could be only a few days before the program is offered.

The Rules Committee stated that the wording should stay the same.

R 338.3665 Performance of activities and functions; delegation.

Ditschman provided an overview of the changes that were made following the last Rules Committee Work Group meeting.

Subrule (b)(iv): Stevenson suggested adding language to include a quality assurance plan.

Kuhns asked what would be the definition of a quality assurance program?

Pawlicki stated that quality assurance program is self-explanatory.

The Rules Committee agreed to have the rule read "….procedures, including a quality assurance plan, governing…."

Subrule (b)(vi): Pawlicki stated that the wording does not address anticipatory compounding in large batches and possible errors by pharmacy technicians.

Stevenson suggested removing the term "compounding."

Pawlicki asked if Stevenson was referring to sterile or non-sterile compounding.

Young stated that compounding should be defined.

Pawlicki agreed that compounding should include both sterile and/or non-sterile.

Kuhns suggested changing the word "does" to "shall."

The Rules Committee agreed to add sterile and nonsterile compounding and change "does" to "shall.".

Subrule (b)(viii): Kurzman stated that there is no research showing an effect on product verification if the pharmacy technician is certified or non-certified.

The Rules Committee agreed to remove "and certification" as this should have been deleted when the reference to the Pharmacy Technician Certification Board (PTCB) was deleted from the proposed rule.

Baran stated that a definition for "technology-assisted" is needed.

Ditschman asked if this term is recognized in the profession.

Pawlicki stated that the language should not be too prescriptive.

Ditschman asked for proposed language to define "technology-assisted final product verification" that includes two pharmacy technicians, a pharmacist giving the order, using technology, which is also broad enough to include future technology.

Baran stated that the word "final" is not used throughout the rule.

Pawlicki stated that it should be inserted before “product verification” throughout the rule.

Ekola stated that the intent was not to use “final” as part of tech-check-tech. Technician assisted does not allow for a pharmacist final verification.

Pawlicki stated that the rule didn’t seem to be written to allow for a second technician. She asked Stevenson if he remembered that the intent of the Rules Committee was to have a second technician. He stated that he agreed that the intent was to have a second technician.

Ekola stated that if “final” is added to the rule, the pharmacist is removed from the scenario.

Ditschman stated that the rule only allows product verification under the delegation and supervision of the pharmacist.

Ditschman asked if the definition could include the dual role or are additional provisions needed.

Pawlicki stated that there are three scenarios that need to be considered: 1) when there are two technicians involved, 2) allowance for rural areas and remove verification, and 3) pharmacist verified orders.

There was a discussion about how this rule would work with the new proposed remote pharmacy legislation. Ditschman stated that the remote pharmacy legislation states that a prescription dispensed by a technician in a remote pharmacy is considered dispensed by the pharmacist. Further, the legislation is very specific that a remote pharmacy is an exception to the statutory limitations on the activities of a pharmacy technician.

Baran stated that the technician who works on the order needs to be recorded.

Jalloul stated that they were under refills.

Pawlicki stated that every tablet that is dispensed is not recorded within a medical facility.

Continuing Education – Public Hearing Comments (A copy of the draft rules and Public Comment Summary are attached)

R 338.3041 License renewals; continuing education requirements; applicability.

Section (1): Ditschman read the public comment to add the definition of “retired pharmacist license” and explained that it is already addressed in the statute.

The Rules Committee agreed to add the word “volunteer” to the rule to clarify that a “special retired pharmacist” refers to the volunteer license in MCL 333.16184.

Section (1)(b): Ditschman read the public comment regarding the wording of "license renewal." She stated that the language is from the statute. She stated that license renewal dates will eventually be based on the original issue dates of the license so each one will be unique.

The Rules Committee agreed to copy the wording in R 338.511 to provide more clarification.

Section (1)(c): Ditschman read the public comment objecting to the opioid training requirements.

Fults stated that nurses are required to complete the same requirement.

Ditschman suggested adding that it is only required for those licensees with a controlled substance license.

The Rules Committee agreed to add the above language.

Ditschman stated that the proposed date of compliance with the rule is March 1, 2020, and the controlled substance rules are currently with the Joint Committee on Administrative Rules (JCAR).

Section (1)(d): Ditschman read the public comment.

Pawlicki asked if this would begin with the first full renewal cycle.

Ditschman stated that it would begin January 1, 2021.

The Rules Committee agreed to the suggested change in the public comment to make the ethics and jurisprudence requirement effective for renewals in 2021.

Section (1)(d)(iii): Ditschman read the public comment to change "pain and symptom management" to "addiction and opioid harm reduction" and stated that this could not be added as the wording currently follows the statute.

R 338.3043 Continuing education courses and programs; standards for approval.

Section (f)(iv): Ditschman read the public comment.

Jalloul clarified the public comment.

The Rules Committee agreed to the suggested change in the public comment, to read "Emergency skills related to the health and safety of the patient."

R 338.3044 Acceptable continuing education for licensees.

Section (a): Ditschman read the public comment to (a) to add additional entities to offer and approve continuing education.

Stevenson asked Baran to clarify the comment. Baran stated that more organizations should be included so they don't have to go before the Board for approval.

Pawlicki stated that opening up the rule to more organizations opens the window to those that don't update content with the changes and that no criteria or standard is being used.

Fults stated that the MHA can be removed from the proposed comment.

Drumm asked if a program needs to be on the list if it has ACPE approval.

The Rules Committee agreed to have only the ACPE listed.

Ditschman read the Sapita/MPA public comment to remove CCAPP.

Stevenson stated that the Board does not currently approve the continuing education in this category, therefore there is no need to change.

Wagenknecht stated that the way the category is written, colleges can provide continuing education without obtaining a separate approval, as long as the school is ACPE accredited.

Ditschman asked if "pharmacy school" needed to be changed to read "educational program" which does not incorporate the entire school.

Pawlicki stated that the first bullet point could be removed.

The Rules Committee agreed to remove MPA as it is ACPE approved, and to change "school" to "pharmacy program" but did not agree to add additional entities.

Section (b): Ditschman read the public comment to change "18" to "16."

Pawlicki and Stevenson questioned why there was a need for a change.

The Rules Committee agreed to leave the rule as written.

Section (d): Ditschman read the public comment to clarify that the preceptor must be with the intern for preceptor hours.

Jalloul stated that the rule does not identify whether the continuing education must be live or not. She also questioned how the individual obtains 120 hours in a preceptorship.

Ditschman asked if the 120 hours of preceptorship is commonly earned in person under the preceptor relationship.

Young stated that “direct” should be added to the rule to clarify that it should be done in person.

Pawlicki and Stevenson agreed that “direct” should be added in order to clarify that in order to count as continuing education, the preceptorship must be in person with the intern.

Section (f): Ditschman read the public comment to remove “10” and replace with “5.”

The Rules Committee agreed to leave the rule as written, as a publication involves a great deal of work.

Section (g): Ditschman read the public comment regarding increasing the credit for taking a specialty examination.

Stevenson stated that obtaining Board of Pharmacy Specialties (BPS) requires a significant amount of time.

Ekola stated that BPS is ACPE accredited.

Ditschman stated that the statute allows the Board the option of allowing a licensee to meet all of the continuing education either through programs and courses or by taking a proficiency examination. The Rules Committee agreed that a specialty examination should not be considered a proficiency examination that is equal to all of the continuing education hours that are required.

Ekola stated that continuing education is already being given for this activity through ACPE.

The Rules Committee agreed to the leave the rule as written.

Section (h): Ditschman read the public comment.

Jalloul stated that the public comment could be withdrawn.

General Rules – Public Hearing Comments (A copy of the draft rules and Public Comment Summary are attached)

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

Section (1)(a): Ditschman read the public comment to add "home of the aged" to the definition of "medical institution." She stated that there is already a definition for "home of the aged."

The Rules Committee agreed to the suggested change in the public comment if a home of the aged is not already in the definition of "health facility."

Section (3): Ditschman read the public comment regarding the phrase "who is on the premises."

Pawlicki stated that the rule doesn't state that direct supervision is required, so having the pharmacist on site would be covered. She questioned what "on the premises" meant.

The Rules Committee agreed to leave "who is on the premises" in the rule.

R 338.501 Definitions.

Section (1)(d): Ditschman stated that this comment would be discussed when USP 795, 797, and 800 were discussed.

Section (1)(j): Ditschman read the public comment questioning the definition of "virtual manufacturer." She explained why it is defined in the statute.

Jalloul stated that the explanation of why the definition is included is sufficient to address the public comment so the comment is withdrawn.

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

Ditschman read the public comment regarding adding a Section (d) regarding the circumstances when the wrong medication is dispensed or a drug recall.

Baran clarified that currently, prescription errors cannot be returned or corrected, and recalls cannot be done legally within a pharmacy

The Rules Committee agreed to the suggested change in the public comment.

Kuhns asked about Schedule 2 recalls and the chain of custody. This provision may open a pharmacy to diversion.

Pawlicki stated that it allows for the pharmacy to act within their facility, but they are not required to act.

Ditschman stated that she will compare the controlled substance rules to confirm consistency.

R 338.505 Inspection of applicants and licensees.

Ditschman read the public comment regarding “at reasonable times.”

The Rules Committee agreed that the rule should remain as written.

Section (e): Ditschman read the public comment to add (f).

Fults clarified the comment stating that having the Department accessing information collected in an internal audit could hinder the type of information that is being sought in an internal audit.

Shook stated that the internal audits are not necessarily licensee or medication involved.

Stevenson stated that the suggested change should be made.

Fults stated that she will provide more specific language.

ADJOURNMENT

Ditschman stated that another Rules Committee Work Group will be scheduled in order to continue working on the Pharmacy – General Rules public comments.

Ditschman adjourned the meeting at 4:00 p.m.

Prepared by:
Stephanie Wysack, Board Support December 2, 2019
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY TECHNICIANS

Filed with the secretary of state on

These rules become effective immediately upon filing with the ~~Secretary~~ **secretary** of ~~State~~ **state** unless adopted under section 33, 44, 45a(6), **of the administrative procedures act** ~~or 48~~ of **1969,** 1969 PA 306**, MCL 24.233, 24.244, or 24.245a**. Rules adopted under these sections become effective 7 days after filing with the ~~Secretary~~ **secretary** of ~~State~~ **state**.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections **16145,** 16148, **16184, 16201, 16204, 16205,** ~~17707,~~ 17731, 17739, 17739a, 17739b, and 17739c~~,~~ of **the public health code,** 1978 PA 368, ~~as amended,~~ MCL 333.16145~~(3)~~, 333.16148, **333.16184, 333.16201, 333.16204, 333.16205,** ~~333.17703,~~ ~~333.17707,~~ 333.17731, 333.17739, ~~333.17339a~~ **333.17739a**, 333.17739b, and **333.**17739c and Executive Reorganization Order Nos. ~~1996-1~~ **1991-9**, 1996-2, 2003-1, and 2011-4, MCL ~~330.3101~~ **338.3501**, 445.2001, 445.2011, and 445.2030)

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

R 338.3651 Pharmacy technician licensure; eligibility; examination.

Rule 1. **Unless exempt pursuant to section 17739a(4) of the code, MCL 333.17739a, while a student enrolled in a pharmacy technician program approved by the board, or a licensee who holds a temporary pharmacy technician license under R 338.3652 and section 17739b of the code, MCL 333.17739b, or holds a limited pharmacy technician license under section 17739c of the code, MCL 333.17739c, an** applicant for licensure **by examination** as a pharmacy technician shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the ~~requirements of the code and the~~ **requirements of section 16174 of the code, MCL 333.16174,** ~~administrative rules promulgated under the code,~~ an applicant shall comply with all of the following requirements:

(a) ~~Have met the requirements specified in section 17739a(1)(b) and (c) of the code, MCL 333.17739a(1)(b) and (c).~~ **Have graduated from an accredited high school or comparable school or educational institution or passed the general educational development test or the graduate equivalency examination.**

(b) ~~Unless exempt under section 17739a(4), MCL 333.17739a(4) of the code,~~ ~~have~~ **Have** passed and provided proof to the department of passing any of the following examinations:

(i) ~~Examinations specified in section 17739a(1)(d)(i) and (ii) of the code, MCL 333.17739a(1)(d)(i) and (ii).~~**The certified pharmacy technician examination given by the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA).**

(ii) A nationally recognized **and administered** pharmacy technician certification examination that ~~covers the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a(1)(d)(iv), and~~ has been approved by the board **under R 338.3654**.

(iii) An employer-based training program examination ~~with a minimum of 100 questions that covers the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a(1)(d)(iv), and~~ **that** has been approved by the board~~, pursuant to both of the following:~~ **under R 338.3654.**

~~(A) The employer submits to the department at least 60 days prior to administering the examination a completed application for approval of the examination, the examination, and the answers to the examination.~~

~~(B) Approval of the examination shall be valid until the examination is changed.~~

(c) Beginning March 16, 2021, an applicant shall meet the English proficiency requirement in R 338.3660.

(d) Beginning March 16, 2021, an applicant shall submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.

R 338.3652 Temporary License.

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

(2) An applicant applying for a pharmacy technician temporary license shall submit a completed application on a form provided by the department, together with the appropriate fee.

(3) The temporary license expires 1 year after the date the temporary license is issued.

R 338.3653 Licensure by endorsement.

Rule 3. (1) An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. **An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.**

(2) ~~In addition to meeting the requirements of the code and administrative rules promulgated under the code, an~~ **An** applicant shall satisfy ~~both~~ **all** of the following requirements:

(a) ~~Have met the requirements specified in section 17739a(1)(b) and (c) of the code, MCL 333.17739a(1)(b) and (c).~~ **Graduate from an accredited high school or comparable school or educational institution or passed the general educational development test or the graduate equivalency examination.**

(b) Satisfy the requirements in section 16174 of the code, MCL 333.16174.

~~(b)~~ **(c)** ~~Meet 1 of the following requirements:~~

~~(i) If~~ **Hold a** ~~licensed~~ **pharmacy technician license or registration by examination in another state that is active and in good standing.** ~~less than 5 years in another state,~~

(d) ~~submit~~ **Submit** proof that the applicant passed 1 of the approved examinations specified in R 338.3651(b).

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

(e) Beginning March 16, 2021, meet the English proficiency requirement in R 338.3660.

(f) Beginning March 16, 2021, submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.

~~(2)~~ **(3)** In addition to meeting the requirements of subrule (1) **and (2)** of this rule, an applicant's license shall be verified**, on a form supplied by the department,** by the licensing agency of ~~another~~ **any** state ~~of the United States~~ in which the applicant holds a current license or ever held a license as a pharmacy technician. ~~This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant.~~ **Verification must be sent directly to the department from the licensing agency and include the record of any disciplinary action taken or pending against the applicant.**

R 338.3654 Examination requirements; passing score; application process.

Rule 4. (1) Except for the Pharmacy Technician Certification Board examination and National Healthcareer Association examination, a nationally recognized pharmacy technician proficiency certification examination and an employer-based training program proficiency examination must be approved by the board.

(2) A nationally recognized pharmacy technician proficiency certification examination shall cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

(3) Applications filed after the effective date of this rule for approval of an employer-based training program proficiency examination shall be offered in association with a specific employer-based training program, meet the accreditation standards of the accrediting body that accredited the program under R 338.3655, and cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

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

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

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

(7) A modification to a proficiency examination during its approval term must be submitted to the department for board approval pursuant to the requirements of this rule.

R 338.3655 Approved pharmacy technician programs.

Rule 5. (1) ~~Pursuant to sections 16171(a), 17739(2), and 17739a(1) of the code, MCL 333.16171(a), MCL 333.17739(2), and MCL 333.17739a(1), a student in an approved pharmacy technician program is exempt from, and not eligible for, licensure while in the program. Any of the~~ **Beginning July 1, 2022,** ~~following pharmacy technician programs are considered board-approved for this purpose:~~

~~(a) A.~~ **all board approved** pharmacy technician ~~program~~**programs, including employer-based training programs, shall be** ~~that is~~ accredited by ~~the accreditation council for pharmacy education (acpe)~~**an accrediting body recognized by the U.S. Department of Education.**

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

~~(b) A pharmacy technician program that is offered by a pharmacist education program that is accredited by the accreditation council for pharmacy education (acpe).~~

~~(c) A comprehensive curriculum-based pharmacy technician education and training program conducted by a school that is licensed pursuant to the Proprietary Schools Act, 1943 PA 148, MCL 395.101 to 395.103.~~

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

~~(2) The contents of the training programs offered under subdivisions (c) and (d) of subrule (1) of this rule include, at a minimum, all of the following:~~

~~(a) The duties and responsibilities of the pharmacy technician and a pharmacist, including the standards of patient confidentiality, and ethics governing pharmacy practice.~~

~~(b) The tasks and technical skills, policies, and procedures related to the pharmacy technician's position pursuant to the duties specified in section 17739(1) of the code, MCL 333.17739(1), and R 338.3665.~~

~~(c) The pharmaceutical-medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.~~

~~(d) The general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.~~

~~(e) The arithmetic calculations required for the usual dosage determinations.~~

~~(f) The essential functions related to drug, purchasing, and inventory control.~~

~~(g) The recordkeeping functions associated with prescriptions or drug orders.~~

~~(3) To gain approval under subdivisions (c) and (d) of subrule (1) of this rule, an application shall be submitted to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required by subrule (2) of this rule.~~

(3) ~~(4)~~ **The pharmacy technician program or employer shall maintain** ~~A~~ **a** record of a student's pharmacy technician training and education**,** ~~shall be maintained by the pharmacy technician training program, employer, or pharmacy~~ specified in ~~subrule (1) of~~ this rule**,** ~~for a period of 2 years and shall include both of the following~~ **for 3 years after a student completes or leaves the program, which shall include all of the following**:

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

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

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

(4) A pharmacy technician program that was board approved before the effective date of these rules must meet the requirements in these rules beginning July 1, 2022 and may apply to maintain board approval by complying with subrule 2 of this rule after the effective date of these rules. Board approvals beginning July 1, 2022, shall be pursuant to the requirements of this rule and the approval expires 5 years after the date of approval. Upon review after 5 years, a pharmacy technician program may be reapproved if it has maintained its accreditation.

(5) A student shall complete a board approved pharmacy technician program within 2 years of beginning the program.

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

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

Rule 7. ~~(1)~~ An applicant **for relicensure** whose ~~Michigan~~ pharmacy technician license has lapsed**,** under the provisions of section 16201(3) or (4) of the code, MCL 333.16201~~(3) or (4)~~, ~~and is not currently licensed in another state~~ **as applicable,** may be relicensed by ~~submitting a completed application on a form provided by the department, together with the appropriate fee, and~~ complying with the following requirements:

(1) ~~Length of period of lapsed license~~ **For a pharmacy technician who has let his or her license lapse and who is not currently licensed in another state:**	Lapsed 0-3 ~~Years~~ **years**	Lapsed more than 3 years
(a) ~~Application and fee~~ **Application and fee**: Submit a completed application on a form provided by the department, together with the requisite fee**.**	√	√
(b) Good moral character: Establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to 338.47.	√	√
(c) Submit fingerprints: Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		√
(d) ~~Continuing education~~ **Continuing education**: Submit proof of having completed 20 hours of continuing education specified in R 338.3661(1)**(d)**~~(a)(i)~~ which was completed within the 2-year period ~~immediately~~ preceding the **date of the** application for relicensure. **However, if the continuing education hours submitted with the application are deficient, the applicant shall have 2 years from the date of the application to complete the deficient hours. The application will be held, and the license will not be issued until the continuing education requirements have been met.**	√	√
(e) ~~Examination~~ **Examination**: Within 2 years of the period ~~immediately~~ preceding the application for relicensure, pass 1 of the examinations specified in R 338.3651(b)(i to iii).		√
(f) Beginning March 16, 2021, an applicant shall submit proof of having completed training in identifying victims of human trafficking as	√	√

required in R 338.3659.		
(g) Verification: Submit verification from the licensing agency of all other states of the United States in which the applicant has ever held a license to practice as a pharmacy technician. Verification must include the record of any disciplinary action taken or pending against the applicant.	√	√

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

~~(a) Submit a completed application on a form provided by the department, together with the requisite fee.~~

~~(b) Submit proof of having completed 20 hours of continuing education or passing an exam specified in R 338.3661(1)(d)(ii) which was completed within the 2-year period immediately preceding the application for relicensure.~~

~~(c) An applicant's license shall be verified by the licensing agency of all other states or territories of the United States in which the applicant holds a current license or ever held a license as a pharmacy technician. If applicable, verification shall include the record of any disciplinary action taken or pending against the applicant.~~

(2) For a pharmacy technician who has let his or her license lapse, but who holds a current and valid pharmacy technician license in another state:	**Lapsed 0-3 years**	**Lapsed more than 3 years**
(a) Application and fee: Submit a completed application on a form provided by the department, together with the requisite fee.	√	√
(b) Good moral character: Establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to 338.47.	√	√
(c) Submit fingerprints: Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		√
(d) Continuing education: Submit proof of having completed 20 hours of continuing education specified in R 338.3661(1)(d) which was completed within the 2-year period preceding the date of the application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant shall have 2 years from the date of the application to complete the deficient hours. The application will be held, and the license will not be issued until the continuing education requirements have been met.	√	√

(e) Beginning March 16, 2021, an applicant shall submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.	√	√
(f) Examination: Within 2 years of the period preceding the application for relicensure, pass 1 of the examinations specified in R 338.3651(b)(i to iii).		√
(g) Verification: Submit verification from the licensing agency of all other states of the United States in which the applicant has ever held a license to practice as a pharmacy technician. Verification must include the record of any disciplinary action taken or pending against the applicant.	√	√

R 338.3659. Training standards for identifying victims of human trafficking; requirements.

Rule 9. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual licensed or seeking licensure shall complete training in identifying victims of human trafficking that meets the following standards:

(a) Training content covering all of the following:

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

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

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

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

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

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

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

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

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

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

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

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

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

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

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

(3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule shall apply for license renewals beginning with the first renewal cycle after ~~the promulgation of this rule~~ **March 16, 2016,** and for initial licenses issued ~~5 or more years~~ after **March 16, 2021** ~~the promulgation of this rule~~.

R 338.3660 English proficiency.

Rule 10. (1) Beginning March 16, 2021, pursuant to section 16174(1)(d) of the code, MCL 333.16174, an applicant for initial licensure whose educational program was taught in a language other than English must demonstrate a working knowledge of the English language. To demonstrate a working knowledge of the English language, the applicant must establish that he or she obtained a total score of not less than 80 on the test of English as a foreign language internet-based test (TOEFL-IBT) administered by the educational testing service.

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

Rule 11. (1) A licensee seeking renewal of a pharmacy technician's license**, who has been licensed for the 2-year period preceding the end of the license cycle,** shall **at renewal,** comply with all of the following**:**

(a) ~~Complete and submit an~~ **Submit a completed** application for renewal **on a form provided by the department together with the requisite fee**.

(b) ~~Pay the required renewal fee.~~ **Beginning March 16, 2021, meet the English proficiency requirement in R 338.3660.**

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

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

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

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

~~(B)~~ **(ii)** ~~Credit for a continuing education program or activity that is identical to a program or activity that the licensee has already earned credit for during the renewal period shall not be granted.~~ **An applicant for license renewal shall not earn credit for taking the same continuing education course or program twice during the same renewal period.**

~~(C)~~ **(iii)** If audited, the licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of continuing education hours earned, sponsor name or the

name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.

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

(v) A continuing education course or program that is offered or approved by any of the following providers is approved by the board:

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

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

(3) A program approved by the ACPE.

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

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

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

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

~~(2)~~ **(3)** Submission of an application for renewal shall constitute the applicant's certification of compliance with this rule. The licensee shall retain documentation of meeting the requirements of this rule for a period of ~~3~~ **4** years from the date of applying for license renewal. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221~~(h)~~.

~~(3) An applicant who was originally licensed in Michigan less than one year before the renewal date is not required to comply with this rule.~~

~~(4) An applicant for renewal who was originally licensed in Michigan more than one year but less than two years before the renewal date shall have accumulated ten hours of continuing education credits pursuant to these rules.~~

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

(5) Effective for applications for renewal that are filed for the renewal cycle that begins 1 year or more after the effective date of this subrule, the applicant shall meet the requirements of this subrule, and the requirements in subrules (1), (3), and (4) of this rule. An applicant for a pharmacy technician license who has been licensed for the entire 2-year period preceding the application for renewal, shall comply with all of the following:

(a) Complete not less than 20 hours of continuing education courses or programs approved by the board under R 338.3662, during the 2 years preceding the application for renewal, as follows:

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

(ii) One hour shall be in pain and symptom management in the practice of pharmacy, which includes but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, and clinical applications as they relate to professional practice.

(iii) One hour shall be in patient safety.

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

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

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

R 338.3662 Format of acceptable continuing education for licensees.

Rule 12. Effective for applications for renewal that are filed for the renewal cycle that begins 1 year or more after the effective date of this subrule, the board shall consider all of the following as acceptable continuing education:

FORMAT OF ACCEPTABLE CONTINUING EDUCATION ACTIVITIES		
(a)	**Completion of an approved continuing education course or program related to the practice of pharmacy. A continuing education course or program is approved, regardless of the format in which it is offered, if it is approved or offered for continuing education credit by any of the following:** • **A pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Canadian Council for Accreditation**	**The number of hours earned is the number of hours approved by the sponsor or the approving organization.** **If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.** **No limitation on the number of hours earned.**

	of Pharmacy Programs (CCAPP). • **A continuing education sponsoring organization, institution, or individual approved by the ACPE.** • **Another state board of pharmacy.** **If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.**	
(b)	**Completion of pharmacy practice or administration courses offered for credit in a pharmacy program accredited by the ACPE or the CCAPP.** **If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.**	**Twelve hours of continuing education are earned for each academic quarter credit earned and 18 hours are earned for each academic semester credit earned.** **No limitation on the number of hours earned.**
(c)	**Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles.** **If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.**	**One hour is earned for each hour devoted to a home study program.** **A maximum of 20 hours per renewal period.**
(d)	**Renewal of a pharmacy technician license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that required in these rules if the licensee resides and practices in another state.**	**Twenty hours are earned.** **A maximum of 20 hours may be earned in each renewal period.**

	If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: the licensee's name, number of hours earned, the sponsor's name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held or the activity was completed.	
(e)	**Initial publication of an article or a chapter related to the practice of pharmacy in either of the following:** • **A pharmacy textbook.** • **A peer reviewed journal.** **If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.**	**Ten hours are earned per publication.** **A maximum of 10 hours may be earned in each renewal period.**
(f)	**Presentation of a continuing education program approved by the board under R 338.3663 or subdivision (a) of this rule that is not a part of the licensee's regular job description.** **If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.**	**Two hours for every 50 minutes devoted to presenting the program.** **A maximum of 10 hours are earned in each renewal period.**
(g)	**Attendance at a pharmacy-related program, which is approved by the board pursuant to R 338.3663.** **If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or course for continuing education credit, and the date on which the program was held or the activity was completed.**	**The number of hours earned is the number of hours approved by the sponsor or the approving organization.** **If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.** **No limitation on the number of hours earned.**

R 338.3663 Continuing education ~~providers;~~ standards for approval.

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

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

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

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

~~(2)~~ **(1)** A continuing education ~~provider~~ **course or program** that is not pre-approved under ~~subrule (1) of this rule~~ **R 338.3661(2)(a)(v) or 338.3662(a)** may be approved by the board~~. To be approved by the board, the provider shall comply with subrules (2), (3), and (4) of this rule,~~ **by submitting to the department a** ~~complete an~~ **completed** application **on a form** provided by the department, ~~and file it with the department for review~~ no later than ~~60~~ **70** days before the **course or** program date**, and no later than 70 days before the next regularly scheduled board meeting**. **A continuing education course or program conducted before board consideration and approval shall be denied approval.** The application and supporting documentation shall include all of the following information:

(a) A program schedule, including **the** date of the program, topics, the name of **all** ~~speaker~~ **speakers**, and break times.

(b) An explanation of how the program is being designed to further educate pharmacy technicians, including a short narrative describing the program content and the criteria for the selection of this topic.

(c) Copies of instructional objectives that have been developed.

(d) Copies of all promotional and advertising materials for the program.

(e) The name, title and address of the program director and a description of his or her qualifications to direct the program.

(f) A description of how the amount of continuing education credit to be awarded for this program was determined.

(g) A description of how participants will be notified that continuing education credit has been earned.

(h) A description of the physical facilities, lab, or pharmacy available to ensure a proper learning environment.

(i) A copy of the curriculum vitae for each instructional staff member.

(j) A description of the delivery method or methods to be used and the techniques that will be employed to assure active participation.

(k) A copy of the post-test instrument that will be used for participant evaluation.

(l) A description of how post tests will be administered, corrected, and returned to participants.

(m) A description of how post-test performance will influence the awarding of continuing education credit.

(n) A description of how attendance will be monitored, including sample documents, and the name of the person monitoring attendance.

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

(3) The continuing education program approved under subrule (2) of this rule shall meet all of the following:

(a) Be an organized program of learning that ~~that will contribute~~ **contributes** to the advancement and enhancement of professional competency and scientific knowledge in the practice of pharmacy and be designed to reflect the educational needs of pharmacy technicians.

(b) Have a scientific and educational integrity and contain generally accepted pharmacy practices.

(c) Have an outline which demonstrates consistency with the course description and reflects the course content.

(d) Be taught in a manner appropriate to the educational content, objectives, and purpose of the program and allow suitable time to be effectively presented to the audience.

(e) Provide instructors who have the necessary qualifications, training, and experience to teach the course.

(f) Provide for active participation and involvement from the participants.

(g) Offer educational materials for each continuing education activity that ~~will enhance~~ **enhances** the participant's understanding of the content and foster applications to pharmacy practice.

(h) Include learning assessments in each activity that allow pharmacy technicians to assess their achievement of the learned content. Completion of a learning assessment is required for continuing education content.

(4) Board approval shall be for a term of 3 years from the date of approval.

(5) An approved continuing education course or program must be reevaluated by the board before any changes during the approval term, including but not limited to changes in the following:

(a) Instructors and speakers.

(b) Continuing education course or program content, title, and number of continuing education hours to be awarded to participants.

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

(d) Emergency changes to instructors and speakers that are unable to be submitted to the board not less than 70 days before the date of the continuing education course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member when proof, acceptable to the department, is submitted with the change supporting the nature of the emergency.

(e) The specific dates that the continuing education course or program is offered do not require further board approval and may be changed without review by the board as long as the presentation dates are within the board's original 3-year term of approval.

~~(4)~~ **(6)** The ~~program~~ provider or sponsor **of a course or program** approved under ~~subrule (2) of~~ this rule shall issue certificates or letters of attendance that include all of the following:

(a) The name of the **applicant and** sponsor.

(b) The name of the program.

(c) The name of the attendee.

(d) The date of the program.

(e) The ~~Michigan~~ **continuing education** approval number ~~as~~ assigned by the department **and current approval term**.

(f) The signature of the person responsible for attendance monitoring and his or her title.

(g) The number and type of hours ~~attended~~ **awarded**.

(7) The provider or sponsor of a course or program shall maintain records of the information contained in subrule (6) of this rule for 5 years after the course or program is offered to participants.

(8) The board may revoke the approval status of any approved continuing education course or program at any time the continuing education course or program fails to comply with these rules.

R 338.3665 Performance of activities and functions; delegation.

Rule 15. In addition to performing the functions described in section 17739(1) of the code, MCL 333.17739~~(1)~~, a licensed pharmacy technician may also engage in ~~reconstituting dosage forms as defined in 17702(4) of the code, MCL 333.17702(4)~~ **the following tasks**, under the delegation and supervision of a licensed pharmacist~~.~~**:**

(a) Reconstituting dosage forms, as defined in 17702(4) of the code, MCL 333.17702.

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

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

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

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

~~(ii) Product verification by a pharmacy technician is limited to pharmacy services provided in a medical institution, as defined in R 338.486.~~

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

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

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

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

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

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – **PHARMACIST** CONTINUING EDUCATION

Filed with the secretary of state on

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

(By authority conferred on the ~~director of the department of community health~~ **department of licensing and regulatory affairs** by sections 16145~~(3)~~**, 16148, 16184, 16201, 16204, 16205,** ~~and~~ 17731, **17737, and 17767** of **the public health code,** 1978 PA 368, MCL 333.16145~~(3) and~~ **, 333.16148, 333.16184, 333.16201, 333.16204, 333.16205,** 333.17731**, 333.17737, and 333.17767,** ~~et seq.~~ and Executive Reorganization Order ~~Numbers~~ **Nos.** ~~1996-1~~ **1991-9**, 1996-2, ~~and~~ 2003-1, **and 2011-4,** ~~being~~ MCL ~~330.3101~~ **338.3501**, 445.2001, ~~and~~ 445.2011**, and 445.2030**)

R 338.3041, R 338.3043, and R 338.3044 of the Michigan Administrative Code are amended, and R 338.3045 is rescinded, to read as follows:

R 338.3041 **License renewals;** ~~Continuing~~ **continuing** education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license **and a special retired pharmacist's license under sections 16201 and 16184 of the code, MCL 333.16201 and 333.16184**. **A licensee seeking renewal shall comply with all of the following:** ~~A renewal shall not be granted unless the applicant has fulfilled the requirements of these rules.~~

~~(2) An applicant who was originally licensed in Michigan less than 1 year before the renewal date is not required to comply with these rules.~~

~~(3) An applicant who was originally licensed in Michigan more than 1 year but less than 2 years before the renewal date shall have accumulated 15 hours of continuing education credits pursuant to these rules. An applicant under this subrule shall be exempt from the requirement of subrule (5) of this rule.~~

(a) Submit a completed application on a form provided by the department, together with the requisite fee.

(b) Beginning with the first renewal cycle after November 13, 2017, an applicant for license renewal shall have completed a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(c) Beginning with the first renewal cycle after January 4, 2019, an applicant for license renewal shall have completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

~~(4)~~ **(d)** ~~Except as otherwise provided in subrules (2) and (3) of this rule,~~ **Beginning in 2020,** an applicant for **license** renewal**,** ~~of a pharmacist's license~~ **who has been licensed for the 2-year period immediately preceding the end of the license cycle,** shall furnish the board with satisfactory evidence that the applicant completed not less than 30 hours of continuing education ~~credits acceptable to~~ **approved by** the board, ~~as provided in~~ **under** R 338.3043 **and R 338.3044**, during the ~~2-year renewal period~~ **2 years immediately preceding the application for renewal, which must comply with all of the following:**~~.~~ ~~An applicant shall comply with subdivisions (5), (6) and (7) of this subrule. This subrule takes effect July 1, 2007.~~

(i) An applicant for license renewal shall complete at least 1 hour of the 30 required hours of continuing education in pharmacy ethics and jurisprudence.

~~(5)~~ **(ii)** An applicant **for license renewal** shall ~~obtain~~ **complete** a minimum of 10 hours of **the 30 required hours of** continuing education ~~credits~~ by attending live courses or programs that provide for direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops. ~~This subrule takes effect July 1, 2007.~~

~~(6)~~ **(iii)** An applicant for license renewal shall complete ~~in each renewal period~~ at least 1 **hour of the 30 required hours of** continuing education ~~hour~~ in pain **and symptom** management, as required under section ~~16204~~ **16204(2)** of the code**, MCL 333.16204(2)**. ~~This subrule takes effect July 1, 2007~~. **Continuing education in pain and symptom management includes, but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.**

~~(7)~~ **(iv)** An applicant **for license renewal shall** ~~may not~~ earn **no** more than 12 hours of continuing education ~~in a day~~ **during a 24-hour period**. ~~This subrule takes effect July 1, 2007.~~

~~(8) Before applying to renew a license, an applicant shall possess certificates confirming continuing education credits awarded that are dated no later than the date the applicant submits the renewal application.~~

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

(2) Submission of an application for renewal constitutes the applicant's certification of compliance with the requirements of this rule. An applicant shall retain documentation of meeting the requirements of this rule for a period of 4 years from the date of applying for license renewal. The board may require an applicant to submit evidence to demonstrate compliance with this rule. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221(h).

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

(4) Except as otherwise stated, this rule takes effect upon promulgation of the rules.

R 338.3043 ~~Education~~ **Continuing education** courses and programs; standards for approval.

Rule 3. ~~(1)~~ The board shall approve continuing education courses or programs pursuant to the **following** standards in this rule~~.~~**:**

(a) A continuing education course or program sponsor shall submit a completed application on forms provided by the department and provide a "Patient Protection" form for any course or program that involves treatment of live patients.

(b) A completed application form shall be submitted to the department at least 70 days prior to the date the continuing education course or program is conducted and 70 days prior to the next regularly scheduled board meeting for the proposed continuing education to be considered for approval by the board. A continuing education course or program conducted prior to board consideration will not be approved.

(c) A continuing education course or program must meet the standards and criteria for an acceptable category of continuing education under this rule and R 338.3044 and must be relevant to health care and advancement of the licensee's pharmacy education.

~~(2)~~ **(d)** ~~An organized~~ **A** continuing education course or program ~~shall~~ **must** be a planned learning program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist. The course or program ~~shall~~ **must** be an individual organized educational experience under responsible sponsorship and capable direction and ~~shall~~ **must** provide qualified instruction.

~~(3)~~ **(e)** A continuing education course or program shall be developed and presented by a sponsor and ~~shall~~ **must** provide all of the following:

~~(a)~~ **(i)** Administrative support ~~which~~ **that** ensures maintenance and availability of adequate records of participation.

~~(b)~~ **(ii)** An adequate budget and resources.

~~(c)~~ **(iii)** Appropriate, qualified, competent teaching staff.

~~(d)~~ **(iv**) A statement of educational goals or measurable behavioral objectives, or both.

~~(e)~~ **(v)** Delivery methods that allow for active participation and involvement.

~~(f)~~ **(vi)** Appropriate, adequate facilities.

~~(g)~~ **(vii)** Evaluations of the participant and the provider.

~~(4) The accreditation council for pharmacy education (acpe) may certify a provider whose course or program was developed and presented in compliance with subrule (3) of this rule. The board may accept such certification as prima facie proof that a course or program meets the standards set forth in subrule (3) of this rule.~~

~~(5) A provider of a course or program that does not fall within subrule (4) of this rule may submit an application for approval. The application shall be submitted on a form provided by the board.~~

~~(6)~~ **(f)** ~~A~~ **The** continuing education course or program ~~shall~~ **must** include study in 1 or more of the following subjects:

~~(a)~~ **(i)** Social, psychological, economic, and legal aspects of health care delivery.

~~(b)~~ **(ii)** The properties and actions of drugs and dosage forms.

~~(c)~~ **(iii)** Etiology, characteristics, and therapeutics of the disease state.

~~(d)~~ **(iv)** Emergency skills **related to the health of the patient in the pharmacy setting.**

~~(e)~~ **(v)** Specialized professional services.

~~(f)~~ **(vi)** Other areas of study that the board finds are designed to maintain or enhance a pharmacist's ability to deliver competent pharmacy services.

(g) Board approval is valid for a 3-year term of approval from the date of approval.

(h) The board shall reevaluate an approved continuing education course or program prior to any changes during the approval term, including but not limited to, changes to either of the following:

(i) Instructors and speakers.

(ii) Course or program content, title, and number of continuing education hours to be awarded to participants.

(i) Subject to subdivision (j) of this rule, all changes to a previously approved course or program must be submitted on required department forms at least 70 days prior to the date the course or program is offered to participants and 70 days prior to the next regularly scheduled board meeting to be considered for approval by the board. Any changes to a submitted and previously approved course or program conducted prior to board reconsideration and approval will not be approved.

(j) Emergency changes to instructors and speakers that cannot be submitted to the board at least 70 days prior to the date of the course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member if proof that is acceptable to the department and that supports the nature of the emergency is submitted with the change.

(k) The specific dates that the course or program will be offered do not require further board approval and may be changed without review by the board if the presentation dates are within the board's original 3-year term of approval.

(l) A sponsor conducting the course or program shall record all of the following on a continuing education certificate or other proof prepared by that sponsor:

(i) The name of the sponsor.

(ii) Continuing education approval number assigned by the department.

(iii) Course title or name of the program.

(iv) Name of the speaker or instructor.

(v) Date the approved course or program was conducted.

(vi) Number and type of continuing education hours awarded.

(vii) Approved sponsor's signature.

(viii) Dates of the current approval term.

(ix) Name of participant.

(m) The board may revoke the approval status of any approved course or program at any time the course or program fails to comply with these rules.

R 338.3044 ~~Computation of credit hours~~ **Acceptable continuing education for licensees**.

Rule 4. ~~(1) If an organized continuing education course or program is offered in segments of 50 to 60 minutes each, 1 hour of credit shall be given for each such segment. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period. For purposes of this rule, continuing education time shall exclude all of the following: Coffee breaks. Breakfast, lunch, or dinner breaks. Any other breaks in the program.~~ **The board shall consider all of the following as acceptable continuing education:**

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

(c)	**Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles.** **If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.**	**One hour will be earned for each hour devoted to a home study program.** **A maximum of 20 hours per renewal period.**
(d)	**Participation as a preceptor for at least 1 pharmacy intern.** **A preceptorship shall be for a minimum of 120 hours and have a 1 intern - to - 1 preceptor ratio. This may involve multiple preceptor relationships at different times.** **If audited, a licensee shall submit written documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.**	**Five hours of continuing education may be earned for a minimum of 120 hours of preceptorship in each renewal period.** **A maximum of 5 hours may be earned in each renewal period.**
(e)	**Renewal of a pharmacy license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that required in these rules if the licensee resides and practices in another state.** **If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: the licensee's name, number of hours earned, the sponsor's name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held or the activity was completed.**	**Thirty hours will be earned.** **A maximum of 30 hours may be earned in each renewal period.**
(f)	**Initial publication of an article or a chapter related to the practice of**	**Ten hours will be earned per publication.**

	pharmacy in either of the following: • **A pharmacy textbook.** • **A peer reviewed journal.** **If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.**	**A maximum of 10 hours may be earned in each renewal period.**
(g)	**Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties (BPS).** **If audited, a licensee shall submit proof of a passing score on the examination.**	**Ten hours may be earned in the year in which the licensee achieves a passing score.** **A maximum of 20 hours may be earned in each renewal period. Credit will not be given for repeating the same examination twice in a renewal period.**
(h)	**Presentation of a continuing education program approved by the board under R 338.3043 or subdivision (a) of this rule that is not a part of the licensee's regular job description.** **If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.**	**Two hours for every 50 minutes devoted to presenting the program.** **A maximum of 10 hours will be earned in each renewal period.**
(i)	**Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043.** **If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or course for continuing education credit, and the date on which the program was held or the activity was completed.**	**The number of hours earned will be the number of hours approved by the sponsor or the approving organization.** **If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.** **No limitation on the number of hours earned.**

~~(2) A pharmacist may earn 1 hour of continuing education credit for each hour devoted to a home study program offered through an acpe-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles, with a maximum of 20~~

~~continuing education hours obtained in each renewal period. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(3) Two hours of continuing education credit may be earned for each hour spent in actually presenting a course or program which has been approved for continuing education credit. A presenter shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(4) Twelve hours of continuing education credit may be earned for each 1 academic quarter hour of postgraduate study of a course approved for continuing education credit given by an academic institution approved by the board.~~

~~(5) Eighteen hours of continuing education credit may be earned for each 1 academic semester hour of postgraduate study of course approved for continuing education credit given by an academic institution approved by the board.~~

R 338.3045 ~~Equivalents; pharmacists residing or practicing in other states.~~ **Rescinded.**

~~Rule 5. (1) An applicant for renewal who resided or practiced in another state that required substantially equivalent continuing education for renewal may obtain renewal of the Michigan license upon verification of licensure in the other state.~~

~~(2) An applicant for renewal who resided or practiced in another state that does not fall within subrule (1) may obtain renewal of the Michigan license upon proof that the applicant acquired continuing education substantially equivalent to that which is otherwise required by these rules.~~

Pharmacy Continuing Education Rules - ORR 2019-022 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
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)
Deeb D. Eid, PharmD, Assistant Profession, Ferris State University
Mary Anne McCoy, PhD, RN, ACNS, ACNP-BC, FAANP, President, Michigan Council of Nurse Practitioners (MICNP)
Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)

Rule 338.3041 **License renewals;** ~~Continuing~~ **continuing** education requirements; applicability

Rule Numbers	Commenter	Comment
Section (1)	Sapita/MPA	"A special retired pharmacist's license" is not defined anywhere in statute or rules and needs to be.
Section (1)(b)	Baran/Ferris	Modify to read: "For license renewals beginning in 2020, an applicant for license renewal shall have completed a 1-time training identifying victims of human trafficking……. The way it is currently written "Beginning with the first renewal cycle after November 13, 2017" is confusing on when the training is actually needed.
Section (1)(c)	Baran/Ferris	Modify to read: "For controlled substance license renewals beginning with the 2021 renewal cycles, an applicant for license renewal shall have completed a 1-time training in opioids and other controlled substances awareness……" Or should rule 338.3041(1)(b) and (c) be completely eliminated as these requirements are not continuing education requirements but are licensing requirements. This is already addressed in rule 338.511 and rule 338.3135.
	McCoy/MICNP	The way the rule is currently written requires all pharmacists seeking renewal of their license to

		obtain the training while the training according to rule 338.3135 is only required for pharmacists seeking renewal of their controlled substance license. Also, the change makes it less confusing for the date it is required to start. Specifically, we have concerns regarding the proposed changes to R 338.3135 that would require opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. In Rule 35, the proposed revisions state that a prescriber or dispenser shall only delegate, allow by a practice agreement, or order the prescribing, dispensing, or administering of a controlled substance to an individual licensed under article 15 who has complied with opioid and controlled substance awareness training. Further, in Rule 35 (5) (a), the draft rules specify that an individual who is renewing his or her license who is a delegate, or allowed by a practice agreement or an order to prescribe, dispense, or administer a controlled substance by a prescriber or dispenser shall complete said training by the end of the first renewal cycle after January 4, 2019, or (b) After September 1, 2019, shall complete the controlled substance training **prior to the application for licensure** (*emphasis added*). Given the next meeting date of July 29, 2019 and taking into consideration any further delays before finalization or posting of revised rules, it would seem that a September 1, 2019 date for initial applicants for a license would not provide them with adequate notice to comply. We respectfully request that the September 1, 2019 date as currently stated in Rule 35 5 (a) & 5 (b) be changed to March 1, 2020 to provide more time for compliance.
Section (1)(d)	Baran/Ferris	Rule 338.3041(d) requires the one hour in pharmacy ethics and jurisprudence be obtained to renew the license in 2020. That means the group of pharmacists renewing with the expiration date of June 30, 2020 will have less than 6 months to obtain this requirement. Would suggest changing the date, the start of rule 338.3041(d) to read **"Beginning in 2021……"** Rule 338.3041(d) changes "during the 2-year renewal period" to "2 years immediately preceding the application for renewal" does this mean if the license is issued for 26 months any continuing education done in months 1 and 2 would not count as continuing education for renewal?

(1)(d)(iii)	Sapita/MPA Eid/Ferris	Add the words “upon request” after the word board, to make this rule more consistent with Rule 2. Consider changing the requirement for “pain and symptom management” to “addiction and opioid harm reduction”. 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 broader 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.
Section (2)	Baran/Ferris	Is asking why the references to 1 year have been deleted.
Rules Committee Response	The Rules Committee	

R 338.3041 **License renewals;** ~~Continuing~~ **continuing** education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license **and a special retired pharmacist’s license under sections 16201 and 16184 of the code, MCL 333.16201 and 333.16184**. **A licensee seeking renewal shall comply with all of the following:** ~~A renewal shall not be granted unless the applicant has fulfilled the requirements of these rules.~~

~~(2) An applicant who was originally licensed in Michigan less than 1 year before the renewal date is not required to comply with these rules.~~

~~(3) An applicant who was originally licensed in Michigan more than 1 year but less than 2 years before the renewal date shall have accumulated 15 hours of continuing education credits pursuant to these rules. An applicant under this subrule shall be exempt from the requirement of subrule (5) of this rule.~~

(a) Submit a completed application on a form provided by the department, together with the requisite fee.

(b) Beginning with the first renewal cycle after November 13, 2017, an applicant for license renewal shall have completed a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(c) Beginning with the first renewal cycle after January 4, 2019, an applicant for license renewal shall have completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

~~(4)~~ **(d)** ~~Except as otherwise provided in subrules (2) and (3) of this rule,~~ **Beginning in 2020,** an applicant for **license** renewal**,** ~~of a pharmacist's license~~ **who has been licensed for the 2-year period immediately preceding the end of the license cycle,** shall furnish the board with satisfactory evidence that the applicant completed not less than 30 hours of continuing education ~~credits acceptable to~~

approved by the board, ~~as provided in~~ **under** R 338.3043 **and R 338.3044**, during the ~~2-year renewal period~~ **2 years immediately preceding the application for renewal, which must comply with all of the following:**~~.~~ ~~An applicant shall comply with subdivisions (5), (6) and (7) of this subrule.~~ ~~This subrule takes effect July 1, 2007.~~

(i) An applicant for license renewal shall complete at least 1 hour of the 30 required hours of continuing education in pharmacy ethics and jurisprudence.

~~(5)~~ **(ii)** An applicant **for license renewal** shall ~~obtain~~ **complete** a minimum of 10 hours of **the 30 required hours of** continuing education ~~credits~~ by attending live courses or programs that provide for direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops. ~~This subrule takes effect July 1, 2007.~~

~~(6)~~ **(iii)** An applicant for license renewal shall complete ~~in each renewal period~~ at least 1 **hour of the 30 required hours of** continuing education ~~hour~~ in pain **and symptom** management, as required under section ~~16204~~ **16204(2)** of the code**, MCL 333.16204(2)**. ~~This subrule takes effect July 1, 2007~~. **Continuing education in pain and symptom management includes, but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.**

~~(7)~~ **(iv)** An applicant **for license renewal shall** ~~may not~~ earn **no** more than 12 hours of continuing education ~~in a day~~ **during a 24-hour period**. ~~This subrule takes effect July 1, 2007.~~

~~(8) Before applying to renew a license, an applicant shall possess certificates confirming continuing education credits awarded that are dated no later than the date the applicant submits the renewal application.~~

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

(2) Submission of an application for renewal constitutes the applicant's certification of compliance with the requirements of this rule. An applicant shall retain documentation of meeting the requirements of this rule for a period of 4 years from the date of applying for license renewal. The board may require an applicant to submit evidence to demonstrate compliance with this rule. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221(h).

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

(4) Except as otherwise stated, this rule takes effect upon promulgation of the rules.

Board Response	The Board

Rule 338.3043 ~~Education~~ **Continuing education** courses and programs; standards for approval.

Rule Numbers	Commenter	Comment
Section (f)(iv)	Sapita/MPA	Should read "Emergency skills related to the health and safety of the patient pharmacy."
Rules Committee Response	The Rules Committee.	

R 338.3043 ~~Education~~ **Continuing education** courses and programs; standards for approval.

Rule 3. ~~(1)~~ The board shall approve continuing education courses or programs pursuant to the **following** standards in this rule~~.~~**:**

(a) A continuing education course or program sponsor shall submit a completed application on forms provided by the department and provide a "Patient Protection" form for any course or program that involves treatment of live patients.

(b) A completed application form shall be submitted to the department at least 70 days prior to the date the continuing education course or program is conducted and 70 days prior to the next regularly scheduled board meeting for the proposed continuing education to be considered for approval by the board. A continuing education course or program conducted prior to board consideration will not be approved.

(c) A continuing education course or program must meet the standards and criteria for an acceptable category of continuing education under this rule and R 338.3044 and must be relevant to health care and advancement of the licensee's pharmacy education.

~~(2)~~ **(d)** ~~An organized~~ **A** continuing education course or program ~~shall~~ **must** be a planned learning program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist. The course or program ~~shall~~ **must** be an individual organized educational experience under responsible sponsorship and capable direction and ~~shall~~ **must** provide qualified instruction.

~~(3)~~ **(e)** A continuing education course or program shall be developed and presented by a sponsor and ~~shall~~ **must** provide all of the following:

~~(a)~~ **(i)** Administrative support ~~which~~ **that** ensures maintenance and availability of adequate records of participation.

~~(b)~~ **(ii)** An adequate budget and resources.

~~(c)~~ **(iii)** Appropriate, qualified, competent teaching staff.

~~(d)~~ **(iv)** A statement of educational goals or measurable behavioral objectives, or both.

~~(e)~~ **(v)** Delivery methods that allow for active participation and involvement.

~~(f)~~ **(vi)** Appropriate, adequate facilities.

~~(g)~~ **(vii)** Evaluations of the participant and the provider.

~~(4) The accreditation council for pharmacy education (acpe) may certify a provider whose course or program was developed and presented in compliance with subrule (3) of this rule. The board may accept such certification as prima facie proof that a course or program meets the standards set forth in subrule (3) of this rule.~~

~~(5) A provider of a course or program that does not fall within subrule (4) of this rule may submit an application for approval. The application shall be submitted on a form provided by the board.~~

~~(6)~~ **(f)** ~~A~~ **The** continuing education course or program ~~shall~~ **must** include study in 1 or more of the following subjects:

~~(a)~~ **(i)** Social, psychological, economic, and legal aspects of health care delivery.

~~(b)~~ **(ii)** The properties and actions of drugs and dosage forms.

~~(c)~~ **(iii)** Etiology, characteristics, and therapeutics of the disease state.

~~(d)~~ **(iv)** Emergency skills **related to the health of the patient in the pharmacy setting.**

~~(e)~~ **(v)** Specialized professional services.

~~(f)~~ **(vi)** Other areas of study that the board finds are designed to maintain or enhance a pharmacist's ability to deliver competent pharmacy services.

(g) Board approval is valid for a 3-year term of approval from the date of approval.

(h) The board shall reevaluate an approved continuing education course or program prior to any changes during the approval term, including but not limited to, changes to either of the following:

(i) Instructors and speakers.

(ii) Course or program content, title, and number of continuing education hours to be awarded to participants.

(i) Subject to subdivision (j) of this rule, all changes to a previously approved course or program must be submitted on required department forms at least 70 days prior to the date the course or program is offered to participants and 70 days prior to the next regularly scheduled board meeting to be considered for approval by the board. Any changes to a submitted and previously approved course or program conducted prior to board reconsideration and approval will not be approved.

(j) Emergency changes to instructors and speakers that cannot be submitted to the board at least 70 days prior to the date of the course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member if proof that is acceptable to the department and that supports the nature of the emergency is submitted with the change.

(k) The specific dates that the course or program will be offered do not require further board approval and may be changed without review by the board if the presentation dates are within the board's original 3-year term of approval.

(l) A sponsor conducting the course or program shall record all of the following on a continuing education certificate or other proof prepared by that sponsor:

(i) The name of the sponsor.

(ii) Continuing education approval number assigned by the department.
(iii) Course title or name of the program.
(iv) Name of the speaker or instructor.
(v) Date the approved course or program was conducted.
(vi) Number and type of continuing education hours awarded.
(vii) Approved sponsor's signature.
(viii) Dates of the current approval term.
(ix) Name of participant.

(m) The board may revoke the approval status of any approved course or program at any time the course or program fails to comply with these rules.

Board Response	The Board

Rule 338.3044

Rule Numbers	Commenter	Comment
Section (a)	Baran/Ferris	**"A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA)."** This should be changed to read "A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA) or Michigan Health and Hospital Association, or national pharmacy organizations, or health system." This would allow for more entities to provide continuing education for pharmacists.
	Sapita/MPA	MPA would like to note that pharmacy school ACPE/CCAPP accreditation process is not similar to ACPE accreditation for CE hours. The accreditation is based on different criteria. Recommend removing the ACPE and CCAPP.
Section (b)	Sapita/MPA	Remove "18" and replace with "16."
Section (d)	Sapita/MPA	MPA does not believe that the CE accredited through preceptorship should be considered Live CE. A preceptor may not always have direct interaction with the student. Some student pharmacists may not interact with a preceptor at all. How will the Board ensure that this will not be abused? Consider removing "1 intern – to- 1 preceptor ratio."

Section (f)	Sapita/MPA	Remove "10" and replace with "5." CE hours should be accredited as home study CE hour.
Section (g)	Clark/bps	While we would support the proposed regulation, we would encourage even broader recognition that has been adopted by Ohio and proposed by Nebraska. Here is the regulatory language currently being considered in Nebraska: *PHARMACY SPECIALTY CERTIFICATION. In lieu of the 30-hour continuing education requirement, the pharmacist may have achieved or maintained certification through the Board of Pharmacy Specialties.* In Ohio, and as proposed in Nebraska, a pharmacist with BPS Board certification is considered to have met the requirement for minimum number of hours of continuing education credits for license renewal. Specific subject requirements for continuing education (e.g. jurisprudence) must still be met, however. Michigan currently has 847 pharmacists with BPS Board certification. We offer the following facts that may be helpful. 1. The Michigan Board of Pharmacy and the Board of Pharmacy Specialties share a common mission of credentialing pharmacists to help protect the public. All BPS board-certified pharmacists are required to maintain an active license to practice pharmacy. 2. As with licensure, the term of board certification is time limited. BPS board certification may be continued either through successfully passing the recertification examination or earning the required number of recertification credits (varies by specialty) from BPS-approved professional development programs. 3. Recertification credits must be provided by BPS-approved professional development providers. Each specialty has from one to three approved programs. 4. BPS standards for professional development providers help ensure a rigorous recertification process. High-stakes assessments are required for all recertification activities, including live programs, which must also meet established BPS criteria. The state of Ohio has recognized BPS board certification as a pathway for pharmacists to demonstrate continuing competency for many years. The Board of Pharmacy Specialties collaborates with Ohio by providing a spreadsheet with a list of BPS-certified pharmacists in Ohio at the time of each license renewal cycle. This spreadsheet helps Ohio reduce costs and time

		associated with auditing pharmacists for compliance with continuing education requirements, since BPS-certified pharmacists are deemed as having met the requirements for the required number of hours of continuing education for license renewal. The Board of Pharmacy Specialties would be pleased to offer similar assistance to the Michigan Board of Pharmacy if a similar regulation were to be adopted.
Section (h)	Sapita/MPA	The two hours for every 50 minutes does not align with ACPE and should be one hour for every 50 minutes. Does presenting the same presentation multiple times count as CE hours for the presenter? Clarification required.
Rules Committee Response	The Rules Committee.	

R 338.3044 ~~Computation of credit hours~~ **Acceptable continuing education for licensees**.

Rule 4. ~~(1) If an organized continuing education course or program is offered in segments of 50 to 60 minutes each, 1 hour of credit shall be given for each such segment. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period. For purposes of this rule, continuing education time shall exclude all of the following: Coffee breaks. Breakfast, lunch, or dinner breaks. Any other breaks in the program.~~ **The board shall consider all of the following as acceptable continuing education:**

ACCEPTABLE CONTINUING EDUCATION ACTIVITIES		
(a)	**Completion of an approved continuing education course or program related to the practice of pharmacy. A continuing education course or program is approved, regardless of the format in which it is offered, if it is approved or offered for continuing education credit by any of the following:** • **A pharmacy school accredited by the Accreditation Council for**	**The number of hours earned will be the number of hours approved by the sponsor or the approving organization.** **If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.**

	Pharmacy Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP). • **A continuing education sponsoring organization, institution, or individual approved by the ACPE.** • **A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA).** • **Another state board of pharmacy.** **If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.**	**No limitation on the number of hours earned.**
(b)	**Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP.** **If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.**	**Twelve hours of continuing education will be earned for each academic quarter credit earned and 18 hours will be earned for each academic semester credit earned.** **No limitation on the number of hours earned.**

(c)	**Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles.** **If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.**	**One hour will be earned for each hour devoted to a home study program.** **A maximum of 20 hours per renewal period.**
(d)	**Participation as a preceptor for at least 1 pharmacy intern.** **A preceptorship shall be for a minimum of 120 hours and have a 1 intern - to - 1 preceptor ratio. This may involve multiple preceptor relationships at different times.** **If audited, a licensee shall submit written documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.**	**Five hours of continuing education may be earned for a minimum of 120 hours of preceptorship in each renewal period.** **A maximum of 5 hours may be earned in each renewal period.**
(e)	**Renewal of a pharmacy license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that**	**Thirty hours will be earned.** **A maximum of 30 hours may be earned in each renewal period.**

	required in these rules if the licensee resides and practices in another state. **If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: the licensee's name, number of hours earned, the sponsor's name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held or the activity was completed.**	
(f)	**Initial publication of an article or a chapter related to the practice of pharmacy in either of the following:** • **A pharmacy textbook.** • **A peer reviewed journal.** **If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.**	**Ten hours will be earned per publication.** **A maximum of 10 hours may be earned in each renewal period.**
(g)	**Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties (BPS).** **If audited, a licensee shall submit proof of a passing score on the examination.**	**Ten hours may be earned in the year in which the licensee achieves a passing score.** **A maximum of 20 hours may be earned in each renewal period. Credit will not be given for repeating**

		the same examination twice in a renewal period.
(h)	**Presentation of a continuing education program approved by the board under R 338.3043 or subdivision (a) of this rule that is not a part of the licensee's regular job description.** **If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.**	**Two hours for every 50 minutes devoted to presenting the program.** **A maximum of 10 hours will be earned in each renewal period.**
(i)	**Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043.** **If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or course for continuing education credit, and the date on which the program was held or the activity was completed.**	**The number of hours earned will be the number of hours approved by the sponsor or the approving organization.** **If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.** **No limitation on the number of hours earned.**

~~(2) A pharmacist may earn 1 hour of continuing education credit for each hour devoted to a home study program offered through an acpe-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles, with a maximum of 20 continuing education hours obtained in each renewal~~

~~period. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(3) Two hours of continuing education credit may be earned for each hour spent in actually presenting a course or program which has been approved for continuing education credit. A presenter shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(4) Twelve hours of continuing education credit may be earned for each 1 academic quarter hour of postgraduate study of a course approved for continuing education credit given by an academic institution approved by the board.~~

~~(5) Eighteen hours of continuing education credit may be earned for each 1 academic semester hour of postgraduate study of course approved for continuing education credit given by an academic institution approved by the board.~~

Board Response	The Board

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 the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the 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 **the public health code,** 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; 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.~~
~~(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 pharmacy~~, 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)(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 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.

(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.

(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, 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.

(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 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.

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 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.
(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 every 18 months.

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.

(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 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.

(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.

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

Testimony/Comments Received:

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

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

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

Section (3)	Baran/Ferris	Delete “inpatients” and replace with “patients of a medical institution” and delete “who is on the premises”. Removing “who is on the premises” does not allow the technicians to remain in the pharmacy working while the pharmacist is at meeting in the hospital or on the floor or etc. This negates the original intent to allow the pharmacist to be in the hospital but not in the pharmacy and let the technicians remain to continue drug preparation for the pharmacist review. This allows the pharmacist of small hospitals to attend meetings and other issues outside of the pharmacy but on the hospital premises. This would enable small hospitals to stay open and serve the public health of the community.
	Sapita/MPA	Do not remove “who is on the premises.”
Rules Committee Response	The Rules Committee	

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

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

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

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

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

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

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

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

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

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the ~~physician or nurse~~ **prescriber** before administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then

a limited number of medications may be stocked at the patient care areas for the administration of first doses. ~~These medications~~ **Medications** ~~shall~~ **must** be provided in a manner that ensures security and immediate availability, such as sealed or secured medication kits, carts, or treatment trays. A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

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

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

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

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

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

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

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

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

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

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

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

Board Response	The Board

Rule 338.501 Definitions.

Rule Numbers	Commenter	Comment
Section (1)(d)	Sullivan/Michigan Surgical Hospital	Requests not adopting USP 797 and 800 and urges the Board to consider having MIOSH adopt USP 800 as an occupational health standard so it can be equally applied to all professions.
Section (1)(j)	Sapita/MPA	"Virtual manufacturer" is not defined in the statute and should be.
Rules Committee Response	The Rules Committee.	

(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.

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

(i) Owns either of the following:

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

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

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

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

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

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

Board Response	The Board

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

Rule Numbers	Commenter	Comment
Add Section (d)	Baran/Ferris	Add to this rule the return of drugs for a manufacturer recall that is down to the patient level or when the wrong medication was dispensed to the patient. This then would align with 21 CFR part 1317. Add: (d) The provisions of subsection (1) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock. This would encourage the removal of harmful drugs.

Rules Committee Response	The Rules Committee.

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.

Board Response	The Board

Rule 338.505 Inspection of applicants and licensees.

Rule Numbers	Commenter	Comment
R 338.505	Baskerville	This draft rule mentions that the approved entity may enter any facility that is eligible for inspection "at reasonable times". The statement about the time needs to be more specific because "reasonable" is largely open to interpretation. Add 9:00 a.m.-5:00 p.m. after the phrase "reasonable times". It should read "…may enter between the reasonable times of 9:00 a.m. and 5:00 p.m., any building…"
Section (e)	Carlson/MHA	Modify to: (e) Research data. (f) Information gathered by a licensed health facility for quality improvement or professional practice review.
Rules Committee Response	The Rules Committee.	

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.

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

Board Response	The Board

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

Rule Numbers	Commenter	Comment
	Eid/Ferris	It is not clear if this training is required for a limited license, see R 338.513.
Section (3)	Sapita/MPA	Rule not consistent with CE rules – consider same verbiage.
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board

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

Rule Numbers	Commenter	Comment
Section (1)	Sapita/MPA	Remove "90 days" and replace with "180 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 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.
Section (2)	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.
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board

Rule 338.515 Internship requirements.

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

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.

(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.

Board Response	The Board

Rule 338.519 Examinations adoption; passing scores; reexamination.

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

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

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

		her theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following: **(a) Enrolled as a student in a pharmacy education program approved by the board.** **(b) Taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination.** **(c) Submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.** (5) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 3 times in a 12-month period. (6) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is later. (7) An applicant shall not sit for either exam specified in subrule (5) or (6) of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), or successfully repeats the foreign pharmacy graduate equivalency examination committee certification program administered by the NABP, and provides proof of completion to the board.
Section (7)	Baran/Ferris	This section as currently written would require the applicant to completely redo the pharmacy degree and not just the sections they failed. Yet a foreign graduate would not have to do so.
Rules Committee Response	The Rules Committee.	

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.

(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.

Board Response	The Board

Rule 338.521 Pharmacist licensure by examination.

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

R 338.521 Pharmacist licensure by examination.

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

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

(a) Earned either of the following:

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

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

(b) Successfully passed the MPJE and the NAPLEX.

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

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

Board Response	The Board

Rule 338.523 Pharmacist license by endorsement; requirements.

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

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.

Board Response	The Board

Rule 338.525 Relicensure of a pharmacist license; requirements.

Rule Numbers	Commenter	Comment
	Eid/Ferris	Questions what happens to applications when the new CE requirements become effective and shouldn't the one-time trainings be required for relicensure?
Section (1)(f) and (g)	Sapita/MPA	Remove "or outside of Michigan."
Rules Committee Response	The Rules Committee.	

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	**License lapsed 0-**	**License lapsed**	**License lapsed 8**

or her license lapse and who is not currently licensed in another state:	**3 years**	**more than 3 years, but less than 8 years**	**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**

Board Response	The Board

Rule 338.531 Pharmacy license; applications; requirements.

Rule Numbers	Commenter	Comment
	Eid/Ferris	Should there be a provision regarding the result when a pharmacist passes away. What happens to the pharmacy license? How often must an inspection be submitted? Are the details of the inspection required to be shared with the state? Is a pharmacy license renewal the same process as the initial process?

	Milenkovich/Much Shelist	USP has indicated they intend to classify all flavorings of conventionally manufactured medications as nonsterile compounding. Fourteen state boards of pharmacy have language on their books excluding flavoring from the definition of compounding. The request is to implement a regulation excepting the safe administration of flavorings added to conventionally manufactured medications from the definition of compounding. The Board can achieve this by narrowing the use of flavoring agents to conventionally manufactured and commercially available liquid medications and by setting conditions to ensure safe administration of flavorings (ie favoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume).
Section (3)	Baran/Ferris	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 this 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."
Rules Committee Response	The Rules Committee.	

R 338.531 Pharmacy license; applications; requirements.

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

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

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

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

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

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

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

(f) A completed self-inspection form.

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

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

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

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

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

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

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

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

Board Response	The Board

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

Rule Numbers	Commenter	Comment
	Eid/Ferris	Should there be a provision regarding the result when a pharmacist passes away. What happens to the pharmacy license? How often must an inspection be submitted? Are the details of the inspection required to be shared with the state? Is a pharmacy license renewal the same process as the initial process?
Section (1)	Kuhns/Portage Pharmacy	Modify as follows: (1) The board shall approve, under section 17748~~a~~ of the code, MCL 333.17748~~a~~, accrediting or inspection organizations ~~or inspection entities~~ for ~~pharmacies~~ entities that compound ~~sterile~~ pharmaceuticals according to standards adopted by reference in R 338.533. Add: (1)(a)"Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.
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.

Section (4)	Baran/Ferris Kuhns/Portage Pharmacy McCloskey/Portage Pharmacy	Add USP Chapter 797 to this to make it consistent with Rule 338.533(1). Delete “and 800”. Adopt USP 800 as most full-time compounders have already built their hazardous rooms. Otherwise agrees with Kuhns comments.
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board

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

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

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

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

		``(V) the date that the drug was compounded; ``(VI) the expiration date; ``(VII) storage and handling instructions; ``(VIII) the National Drug Code number, if available; ``(IX) the statement `Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement `Office Use Only'; and ``(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient." Also, the label needs to meet the requirements in Rule 338.582, and it would be easier to state the rule number and not all the details in the rule.
Section (7)(a)	Carlson/MHA	"Supervision" is not defined in the Code or the rules. The Code and rules generally use "personal charge" in reference to needing the immediate presence of a pharmacist. Modify supervision to personal charge.
Rules Committee Response	The Rules Committee.	

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 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.

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

Board Response	The Board

Rule 338.534 Inspections.

Rule Numbers	Commenter	Comment
	Carlson/MHA	Under the "Inspections of applicants and licensees" section, the MHA feels the inspection should also exclude data gathered by the licensed health facility for quality improvement or professional practice review purposes. The collection of quality improvement data enables providers to work to improve patient safety and reduce the incidence of adverse events. This data could be incorrectly interpreted, which may deter providers from collecting data for quality improvement purposes. Professional practice evaluation is the process by which a health facility, using its own medical staff, performs a peer review of a privileged practitioner's professional practice for performance improvement and to ensure safe and high-quality patient care. The data should 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. Also, add the Joint Commission to (4).
Section (4)	Sapita/MPA	Remove "the NABP-VPP" replace with "a board approved accrediting organization."
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board

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

Rule Numbers	Commenter	Comment
Section (1)	Kuhns/Portage Pharmacy	Add "or outsourcing facility" to (1): A sterile compounding pharmacy or outsourcing facility.
Section (3)		Add the following: (3) An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-10).
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board

Rule 338.536 Housing of a pharmacy.

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	The 150 square feet requirement has been in the rule for over 30 years. Given the increase in technology and the number of drugs requiring an increase in space this minimum should be at least 250 square feet for any new licenses issued. 250 square feet is used by a couple of the great lake states.
	Baskerville	This rule states that there should be not less than 10 feet of free counterspace, but it does not consider the amount of technology that a pharmacy utilizes or the technicians. A minimum of 10 feet is too small when you account for computers, printers, fax machines, and separate workspaces for the technicians. Add: not less than 16 feet of free workspace.
Section (3)	Baran	Add exception here for restroom breaks and assisting patients in the over the counter purchases.
Rules Committee Response	The Rules Committee.	

R 338.536 Housing of a pharmacy.

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

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

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling. All partitions must be of substantial construction and must be securely lockable so that drugs and devices that can be sold only by a pharmacist will be unobtainable during the absence of the pharmacist. Only the area of the premises owned, leased, used, or controlled by the licensee may be identified by the terms "drugstore," "apothecary," or "pharmacy," or by use of a similar term or combination of terms as listed in

section 17711(2) of the code, MCL 333.17711(2). A pharmacy department must be locked when the pharmacist is not on the premises.

Board Response	The Board

Rule 338.537 Professional and technical equipment and supplies.

Rule Numbers	Commenter	Comment
Section (2)	Baskerville	This rule does not give any guidelines about the refrigerator and it does not give any requirements on a freezer. Add: a refrigerator that has a maximum temperature of 35 degrees Fahrenheit and a freezer that has a maximum temperature of 0 degrees Fahrenheit if necessary, of reasonable capacity located in the pharmacy department.
Rules Committee Response	The Rules Committee.	

R 338.537 Professional and technical equipment and supplies.
Rule 37. A pharmacy must be equipped with all of the following:
(a) Drawers, shelves, and storage cabinets.
(b) A sink that has hot and cold running water.
(c) A refrigerator of reasonable capacity located in the pharmacy department.
(d) Current editions or revisions of the Michigan pharmacy laws and rules, and not less than 2 current or revised pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. A current electronic version of pharmacy laws, rules, and pharmacy reference texts, including accessible internet versions, meets the requirements of this subrule.

Board Response	The Board

Rule 338.538 Closing pharmacy.

Rule Numbers	Commenter	Comment
Section (d)	Baran/Ferris	Change this to 14 days to coincide with federal requirements.
Rules Committee	The Rules Committee.	

Response	

R 338.538 Closing pharmacy.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

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

Board Response	The Board

Rule 338.559 Relicensure.

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

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.

Board Response	The Board

Rule 338.561 Pharmacy as wholesale distributor; licensure.

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

R 338.561 Pharmacy as wholesale distributor; licensure.

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

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

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

Board Response	The Board

Rule 338.563 Wholesale distributor; application for licensure; requirements.

Rule Numbers	Commenter	Comment
Section (2)(i)(B)	Roath/SpartanNash	While the training requirements under Rule 63, Subrule (2)(i)(B)are advisable to a person in the facility manager position, a lack of accredited or universally recognized training program makes the path to compliance with this rule unclear. Given that no accredited program exists, employers

	Sapita/MPA	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. MPA is not aware of any specific training programs that cover all listed topics and believes this responsibility should lie with the wholesaler rather than the board.
Rules Committee Response	The Rules Committee.	

R 338.563 Wholesale distributor; application for licensure; requirements.

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

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

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

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

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

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

(e) A completed compliance checklist.

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

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

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

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

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

(1) A high school diploma.

(2) A general education development certificate (GED).
(3) A parent-issued diploma for home schooled individuals.
(4) Completion of post-secondary education, including an associate's, bachelor's, or master's degree.
(B) Completion of a training program that includes, but is not limited to, all of the following subjects:
(1) Knowledge and understanding of laws in this state and federal laws relating to the distribution of drugs and devices.
(2) Knowledge and understanding of laws in this state and federal laws relating to the distribution of controlled substances.
(3) Knowledge and understanding of quality control systems.
(4) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.
(5) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.
(C) Experience equal to either of the following:
(1) A minimum of 1 year of work experience related to the distribution or dispensing of prescription drugs or devices where the responsibilities included, but were not limited to, recordkeeping.
(2) Previous or current employment as a designated representative of a wholesale distributor certified by the VAWD of NABP.

Board Response	The Board

Rule 338.582 Prescription drug labeling and dispensing.

Rule Numbers	Commenter	Comment
Section (3)	Baran/Ferris	Need to delete "**or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products**" from the rule. The rule was created before computer software was standard practice in pharmacy over 30 years ago. This terminology is no longer used on prescription labels because computers made it obsolete.
Section (3)	Kurzman/NACDS	Delete (3) for the following reasons: Under R 338.582 (2) and (3), the Board proposed rule changes that address labeling requirements when a brand vs. generic drug is dispensed. Language under subrule (2)(g) and (i) specifies that prescription labels must include the medication name and the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label". Notably, the proposed language further specifies under subrule (3) that when "a drug is dispensed that is not the brand prescribed… the prescription label must indicate both the name of the brand prescribed and the

		name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products." However, if the if the prescriber indicates "do not label"… [the] subrule does not apply…" We are concerned that altogether, the language in subrule (2)(g) and (i) and in subrule (3) is duplicative and may lead to confusion. To simplify and clarify this issue, we recommend that subrule (3) be stricken entirely as that provision is redundant to the requirements outlined in subrule (2)(g) and (i).
Section	Eid/Ferris	Although being worked on within the Pharmacy Technician specific rules, consider the following for both this section and the Pharmacy Technician rule set. Tech-check-tech, or as some states are now calling it "accuracy checking" or "technician product verifiction" has been successfully and safely practiced in some states for decades. There are approximately 20 studies to date on the topic in various settings including community based and health systems. **Adams et al** reviewed and demonstrated safety data, including that results of 11 studies published since 1978 indicate that technicians' accuracy in performing final dispensing checks is very comparable to pharmacists' accuracy (mean ± S.D., **99.6%** ± 0.55% versus **99.3%** ± 0.68%, respectively. **Frost et al** also reviews data in the community setting and also showed that in 2 studies that reported accuracy rates, pharmacy technicians performed at least as accurately as pharmacists (**99.445** vs **99.73%,** P = .484; **99.95** vs **99.74**, P < .05). In addition, there are multiple pilot and research programs in states such as Wisconsin, Tennessee, Iowa, South Dakota, and more which have been studying the workflow and outcomes of implementing these models. I encourage the board and other stakeholders to move forward on this as it will only help to improve patient care initiatives and allow for pharmacists to spend more time with patients as demonstrated by **Andreski et al.** I'd also encourage the board to refer to **Adams** for deliberations of the Idaho regulatory board on advancing technician practice, which an example from.
Rules Committee Response	The Rules Committee.	

R 338.582 Prescription drug labeling and dispensing.

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

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

(a) Pharmacy name and address.

(b) Prescription number.

(c) Patient's name.

(d) Date the prescription was most recently dispensed.

(e) Prescriber's name.

(f) Directions for use.

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

(h) The quantity dispensed, if applicable.

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

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

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

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

Board Response	The Board

Rule 338.584 Noncontrolled prescriptions.

Rule Numbers	Commenter	Comment
Section (4)	Baran/Ferris	Modify to: (4) A noncontrolled prescription is valid for 1 year from the date the prescription was issued. This makes it clear this only applies to noncontrolled prescriptions.

Rules Committee Response	The Rules Committee.

R 338.584 Noncontrolled prescriptions.

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

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

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

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

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

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

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

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

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

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

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

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

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

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

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

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

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

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

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

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

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

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

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

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

Board Response	The Board

Rule 338.585 Customized patient medication package.

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

Response	

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.

Board Response	The Board

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

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	Delete (2) entirely as this method is outdated by the use of computers. This part is more than 40 years old with no one using this process today.
Section (3)(vii) and (4)(vii)	Sapita/MPA	Remove "name of the manufacturer."
Section (6)	Sapita/MPA	Subrule (2) should be included in this section.

Rules Committee Response	The Rules Committee.

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.

Board Response	The Board

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	The Rules Committee.	

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.

(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 and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:

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

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

(iii) The type of transaction.
(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.
(v) The name of the patient for whom the drug was ordered.
(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.
(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:
(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(j).
(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).
(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.
(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours
(e) The automated device is located in a dispensing prescriber's office.
(9) A copy of all policies and procedures related to the use of an automated device must be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

Board Response	The Board

Rule 338.589 Professional responsibility; "caregiver" defined.

Rule Numbers	Commenter	Comment
Section (4)(d)	Carlson/MHA	A requirement to document the consultation (or the reason why consultation was not completed) should be included. There are a number of reasons for this … not the least of which is to protect the pharmacist from liability should a patient claim he/she was not warned as required by this rule.
Section (5)	Baran/Ferris	There is no longer an exception in R 338.486(3).
Rules Committee Response	The Rules Committee.	

R 338.589 Professional responsibility; "caregiver" defined.

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

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

(a) The prescription appears to be improperly written.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Board Response	The Board

Rule 338.590 Hospice emergency drug box.

Rule Numbers	Commenter	Comment
Section (11)	Sapita/MPA	After “prescriptions” add issued by an appropriate prescriber” and remove “of the attending physician.
Rules Committee Response	The Rules Committee.	

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.

Board Response	The Board