MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
MAY 17, 2022

The Michigan Board of Pharmacy Rules Committee Work Group met on May 17, 2022. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 8:36 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph.
Charles Mollien, PharmD, JD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Members Absent: None

Staff Present: Andria Ditschman, Departmental Specialist,
Boards and Committees Section
Andrew Hudson, Manager, Pharmacy & Drug Monitoring Section
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support Technician,
Boards and Committees Section

Public Present: Rose Baran - self
Farah Jalloul, PharmD, MBA – Michigan Pharmacists Association (MPA)

WELCOME

Ditschman went over the agenda and what the Rules Committee would be covering.

RULES DISCUSSION

Pharmacy – Controlled Substances (A copy of the draft, used during today's discussion, is attached)

Scheduling of substances: Ditschman stated that the Board's adoption of the Federal controlled substances schedules resulted in adoption of a narrower definition of Synthetic Cathinones. She stated that MCL 333.7212(1)(x) has a broader definition of Synthetic Cathinones than the Federal definition. She asked the Rules Committee if this should be included as an exception to the Federal schedule.

The Rules Committee agreed that the broader definition from the state statute would be preferable. The broader state definition will be listed as an exception to the Federal schedule.

Ditschman stated that she will provide a chart to the Board when it discusses the exceptions to the Federal controlled substances schedule.

HB 5877 of 2022: Ditschman stated that this has not passed yet, but it is written to remove marihuana and pharmaceutical-grade cannabis as a schedule 1 and modifies the penalties. She asked the Rules Committee if they would like to address the scheduling of marihuana.

Discussion was held.

The Rules Committee agreed to wait for the bill to run its course and not reschedule marihuana at this time.

R 338.3161 Controlled substance prescriptions.

Subdivision (1)(d): Ditschman stated that she had received questions regarding the Board's intent of this rule. She read the previous rules.

Mollien stated that the language should be changed back to what was used previously.

The Rules Committee agreed to change the language back to clarify that a paper prescription complies if it contains preprinted numbers, representing the quantity, next to a box or line that the prescriber can check.

Subdivision (1)(b): Baran stated that "telephone number or pager number" were struck out, but they are required under MCL 333.7109.

Mollien asked if the Board had the authority to clarify these requirements.

Ditschman stated that the statute was clear, and that the language should be included.

The Rules Committee agreed to add the language back into the subdivision.

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.

Subrules (c), (h), and (k): Baran stated that the rule was inconsistent within the Pharmacy – General Rules. The Pharmacy – General Rules state 5 years retention. She stated that prescriptions have always been 5 years, but invoices are different.

Mollien stated that language for controlled and non-controlled substances should be the same. He suggested using 2 years to be consistent.

The Rules Committee agreed to use 2 years for records, except for sales receipts which will be 90 days.

Discussion was held regarding changing the introduction paragraph of the rule to delete "responsible for the automated device" and add "non-patient" before records.

Discussion was held how this affected the entire rule. Subrules (a) through (k) were correct as written except for subrule (c).

The Rules Committee agreed with the above changes and to delete (c).

Subrule (k): Ditschman asked if (k) could also be deleted due to the changes to the other provisions.

The Rules Committee agreed that it no longer applied and that it could be removed. This also needed to be addressed in the Pharmacy – General Rules and non-controlled substances.

Discussion was held regarding identifying the different types of sales receipts.

Mollien suggested breaking the rule up into two parts; (1) will address invoices and acquisition records and (2) will address patient sales receipts.

The Rules Committee agreed with the suggested change.

Ditschman will work on reorganizing for review at the next Rules Committee Work Group meeting.

R 338.3141 Thefts and diversions.

Ditschman stated that at the prior Rules Committee Work Group meeting, the Rules Committee directed that this section should be discussed by the Board regarding requiring a one-day notice of suspected loss being sent to the department.

Discussion was held.

The Rules Committee felt that discussion was no longer necessary and that the rule should stay as is. Reporting to the Drug Enforcement Agency is sufficient. Requiring additional notification to the department causes a distraction to the facility in completing their investigation.

R 338.3154 Medication records in medical institutions.

Ditschman stated that this was a long rule and asked the Rules Committee if the subject matter could be divided into two rules.

Mollien stated that it was all necessary in this rule.

R 338.3161 Controlled substance prescriptions.

Subdivision (1)(b): Mollien stated that “professional designation” could be moved to subrule (6).

The Rules Committee agreed with the suggested change.

R 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Ditschman stated that since the Code was modified to all prescriptions dispensed by a dispensing prescriber as an automatic exception to electronic transmission, it no longer should be listed in the rule as a basis for a department exception.

Mollien stated that the two new exceptions addressed in the Code were prescriptions used in home-based dialysis and electronic prescriptions dispensed by a dispensing prescriber.

R 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Subdivision (1)(a): Baran stated that this rule should be written to be consistent with the federal rule regarding mail.

Discussion was held regarding possible new language.

Mollien stated that the rule should clarify that a prescriber has 7 days to follow up and that includes mail postmarked within 7 days after the date the prescription was dispensed.

Ditschman will work on language so that it is consistent with federal language for the Rules Committee to review at the next Rules Committee Work Group meeting.

R 338.3167 Dispensing schedule 5 substances without prescriptions.

Mollien stated that these are required to be put in a logbook. He asked the Rules Committee if they felt that scans of the logbook would be sufficient to meet this requirement.

The Rules Committee agreed that scans would meet the requirement.

R 338.3185 Discontinuances and transfers

Poynter asked if there was a need to include language in the rule about returning the registration to the DEA, if that is the DEA requirement.

Mollien stated that the rule could be shortened to read “A licensee who wants to discontinue or transfer business activities or a professional practice altogether or only with respect to controlled substances shall return the state-controlled substances license to the department.”

Poynter suggested adding the 15-day notice language.

Mollien stated that it should be 15 days in advance.

Hudson agreed with the proposed new language.

The Rules Committee agreed with the proposed new language.

Pharmacy Technicians (A copy of the draft, used during today’s discussion, is attached)

R 338.36 Definitions.

Ditschman stated that she added definitions to this rule as definitions were not previously included in the rules.

The Rules Committee agreed with the language as presented.

R 338.3651 Pharmacy technician licensure; eligibility; examination.

Ditschman asked the Rules Committee if the rule should address a minimum passing score. Many rule sets use 75%.

Taylor agreed that there should be a standard.

Ditschman asked if the score should apply to all examinations approved by the board or just the employer-based programs.

Mollien stated that Pharmacy Technicians University (PTU) requires a score of 75%. PTU is used by many of the employer-based programs that are approved by the board.

The Rules Committee agreed to use 70% as a minimum but would like to make sure that this is also discussed with the board.

R 338.3654 Examination requirements; board approval; approval process.

Ditschman stated that there was a date under subrule (6), as to when it becomes effective. She asked the Rules Committee if there should be a subrule that provides a date of when it should be completed.

Discussion was held.

The Rules Committee did not agree to add a date of when the approval should be completed.

Subrule (6): Mollien stated that PTCB and NHA should be added to this subrule as exceptions because they are not being approved by the board.

The Rules Committee agreed with Mollien's suggestion.

R 338.3655 Approved pharmacy technician programs.

Ditschman stated that MPA offered a preparation course to employers and are advertising that it is board approved. She stated that the Code does not address programs, only examinations. She asked the Rules Committee if a rule should be added for program approval, other than proprietary or employer-based programs.

Discussion was held about expanding the rule, which in turn could affect temporary licensure.

Mollien clarified that if a temporary license was available, training does not matter.

The Rules Committee agreed to not expand the rule.

Jalloul asked if MPA's program required passing the PTCB examination, once completed, would MPA apply for board approval.

Ditschman clarified that MPA would not apply for approval, the employer that is using the MPA examination would apply for approval, indicating that they use the MPA training in their pharmacy program.

The Rules Committee agreed to have further discussion about approving just a program, without an examination, requiring the applicant to complete either the PTCB or NHA examination upon completion, to obtain full licensure.

ADJOURNMENT

Ditschman stated that another Rules Committee Work Group meeting was needed to continue working on the Pharmacy – General Rules, Pharmacy Technicians, and Controlled Substances drafts.

Ditschman adjourned the meeting at 10:30 a.m.

Prepared by:
Stephanie Wysack, Board Support Technician May 23, 2022
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY – CONTROLLED SUBSTANCES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the board of pharmacy by sections 7106, 7109, 7203, 7216, 7301, 7303, 7303a, 7321, 7333, 7333a, and 17754 of the public health code, 1978 PA 368, MCL 333.7106, 333.7109, 333.7203, 333.7216, 333.7301, 333.7303, 333.7303a, 333.7321, 333.7333, 333.7333a, and 333.17754, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3101, etc of the Michigan Administrative Code is amended as follows:

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

(a) “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.

(b) “Board” means the board of pharmacy.

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

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

(e) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by an individual 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 nonrepudiation so that the signature may not be rejected based on its validity.

R 338.3102 Definitions; I to P.

Rule 2. As used in these rules:

(a) "Inventory" means all stocks in finished form of a controlled substance that are manufactured or otherwise acquired by a licensee, whether in bulk or commercial containers or contained in pharmaceutical preparations in the possession of the licensee.

(b) "Licensee" means a person who is licensed pursuant to section 7303 of the code, MCL 333.7303.

(c) "Michigan automated prescription system (MAPS) claim form" means a form, to be determined by the department, that is in the format and includes the information as specified by the American Society for Automation in Pharmacy (ASAP) 4.1 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.

(d) "National drug code number (NDC)" means a number that identifies the labeler, vendor, product, and package size and is assigned to each drug product listed under section 510 Registration of Producers of Drugs and Devices, of the Federal Food, Drug, and Cosmetic Act (FDCA) of 2017, 21 USC 360.

(e) "Officer" means a federal, state, county, or local law enforcement officer who enforces the laws of this state.

(f) "Patient identifier" means all of the following information about a patient:

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

(iv) Any 1 of the following identification numbers:

(A) A state-issued driver's license number obtained from a state-issued driver's license.

(B) A state-issued identification number obtained from a state-issued photo identification card.

(C) A federal passport number obtained from a federal passport.

(D) The number zero. Zeroes must be entered as the identification number, if the positive identification presented for the patient or client does not include a license number, identification number, or passport number as listed in subparagraphs (A) to (C) of this paragraph, the patient is under the age of 16, or the animal's owner cannot be identified.

(g) "Positive identification" means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification includes an identification card issued by a governmental agency, if the identification card meets the requirements of this rule.

(h) "Medical institution" means the term as defined in R 338.486.

(i) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy, as defined in section 17707 of the code, MCL 333.17707.

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

(a) "Readily retrievable" means a record which is kept so that it can be separated from all other records within 48 hours and in which a listed controlled substance is marked with an asterisk, redlined, or in some other manner visually identifiable apart from the other substances listed in the record.

(b) "Substance" means a controlled substance unless the context indicates otherwise.

R 338.3108 Terms defined in code.

Rule 8. Unless otherwise defined in these rules, the terms defined in the code have the same meaning when used in these rules.

PART 2. SCHEDULES

R 338.3111 Schedules; federal controlled substance schedules adopt by reference; exceptions.

Rule 11. (1) The board approves and adopts by reference the complete list of drugs and other substances that are considered controlled substances under the Controlled Substance Act (CSA) of 1970, 21 USC 801, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15, except for those drugs or other substances specifically excepted by this state's laws enacted after the effective date of these rules or as listed in subrule (3) of this rule.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm, or at 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

(3) The following drugs and other substances are scheduled as follows:

(a) Marijuana including pharmaceutical-grade cannabis, as those terms are defined in parts 71 and 81 of the code, MCL 333.7101 to 333.7125 and MCL 333.8101 to 333.8119, is a schedule 2 controlled substance if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the code and as allowed by federal authority but only for the purpose of treating a debilitating medical condition as that term is defined in section 3(b) of the Michigan medical marihuana act, 2008 IL 1, MCL 333.26423, and as allowed under the code.

(b) Tianeptine sodium by whatever official, common, usual, chemical, or brand name designated is a schedule 2 controlled substance.

(c) Gabapentin by whatever official, common, usual, chemical, or brand name designated is a schedule 5 controlled substance.

(d) Loperamide is not a scheduled controlled substance in this state.

(e) Pentazocine is a schedule 4 controlled substance.et

(f) Brorphine is a schedule 1 controlled substance.

(g) **Salvia divinorum all parts of the plant presently classified botanically as salvia divinorum, whether growing or not; the leaves and seeds of that plant; any extract from any part of that plant; and every compound, salt, derivative, mixture, or preparation of that plant or its leaves, seeds, or extracts is a schedule 1 substance.**

(h) Isomers are a scheduled 1 substance and includes the optical, position, and geometric isomers.

(i) Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of cannabis and synthetic substances, derivatives, and their isomers with similar chemical structure or pharmacological activity, or both, such as the following, are schedule 1 controlled substances:

(i) /\1 cis or trans tetrahydrocannabinol, and their optical isomers.
(ii) /\6 cis or trans tetrahydrocannabinol, and their optical isomers.
(iii) /\3,4, cis or trans tetrahydrocannabinol, and their optical isomers.

(j)~~(g)~~ Except in subdivision ~~(h)~~**(k)** of this subrule, ephedrine, a salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is included in schedule 5.

~~(h)~~**(k)** A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is not included in schedule 5 if the drug product meets all of the following criteria:

(i) May lawfully be sold over the counter without a prescription under federal law.

(ii) Is labeled and marketed in a manner consistent with the pertinent over-the-counter tentative final or final monograph.

(iii) Is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse.

(iv) Is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement.

(v) The drug product is 1 of the following:

(A) A solid dosage form, including, but not limited to, a soft gelatin caplet that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose and is packaged in blister packs with not more than 2 tablets or caplets per blister.

(B) An anorectal preparation containing not more than 5% ephedrine.

(C) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria:

(I) Contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids in applicable regulations adopted by the Federal Food and Drug Administration (FDA) and contains no other controlled substance.

(II) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids.

(III) Is packaged with a prominent label securely affixed to each package that includes all of the following:

(1) The amount in milligrams of ephedrine in a serving or dosage unit.

(2) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.

(3) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable regulations adopted by the FDA.

(4) That improper use of the product may be hazardous to an individual's health.

(l) A synthetic cannabinoid as described in this subdivision is a scheduled 1 substance. As used in this subdivision, "synthetic cannabinoids" includes any material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules II through V, is not approved by the federal food and drug administration as a drug, and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or

geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:

(i) Any compound containing a 3-(1-naphthoyl)indole structure, also known as napthoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-007, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398, AM-1220, AM-2201, and WIN-55, 212-2.

(ii) Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure, also known as napthylmethylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-175, and JWH-184.

(iii) Any compound containing a 3-(1-naphthoyl)pyrrole structure, also known as naphthoylpyrroles with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the pyrrole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-370, JWH-030.

(iv) Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indene ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-176.

(v) Any compound containing a 3-phenylacetylindole structure, also known as phenacetylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-8 (SR-18), JWH-250, JWH-203, JWH-251, and JWH-302.

(vi) Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure, also known as cyclohexylphenols, with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, Rendered Thursday, March 17, 2022 Page 10 Michigan Compiled Laws Complete Through PA 34 of 2022 □ Courtesy of www.legislature.mi.gov whether or not substituted on the cyclohexyl

ring to any extent. Examples of this structural class include but are not limited to: CP-47,497 (and homologues(analogs)), cannabicyclohexanol, and CP-55,940.

(vii) Any compound containing a 3-(benzoyl)indole structure, also known as benzoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: AM-694, pravadoline (WIN-48,098), RCS-4, AM-630, AM-679, AM-1241, and AM-2233.

(viii) Any compound containing a 11-hydroxy-/\8-tetrahydrocannabinol structure, also known as dibenzopyrans, with further substitution on the 3-pentyl group by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkyethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group. Examples of this structural class include but are not limited to: HU-210, JWH-051, JWH-133.

(ix) Any compound containing a 3-(L-adamantoyl)indole structure, also known as adamantoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the adamantyl ring system to any extent. Examples of this structural class include but are not limited to: AM-1248.

(x) Any other synthetic chemical compound that is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring cannabinoids that is not listed in schedules II through V and is not approved by the federal food and drug administration as a drug.

R 338.3132 Controlled substance license.

Rule 32. (1) A person who manufactures, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall apply for a controlled substance license by submitting to the department a completed application on a form provided by the department along with the requisite fee.

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, 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 controlled substance license. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

(3) Except as otherwise provided in subrules (8) and (9) of this rule, a separate controlled substance license is required in each of the following circumstances:

(a) For each principal place of business or professional practice where the applicant stores, manufactures, distributes, prescribes, or dispenses controlled substances.

(b) Manufacturing and distributing a controlled substance in schedules 2-5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to manufacture a controlled substance listed in schedules 2 to 5 may also conduct chemical analysis and research with a substance that is listed in the schedules under the same controlled substance license.

(c) Dispensing a controlled substance listed in schedules 2 to 5. A prescriber or practitioner who is licensed in this state to prescribe or dispense controlled substances listed in schedules 2 to 5 may also prescribe, dispense, administer, and conduct research with those substances under the same controlled substance license.

(d) Conducting research and instructional activity with a controlled substance listed in schedule 1. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to conduct research with controlled substances listed in schedule 1 may do both of the following:

(i) Manufacture the specific substances as set forth in the research protocol that is filed and approved by the FDA and the DEA pursuant to the provisions of 21 CFR 1301.18 and submitted to the department with the application for licensure.

(ii) Distribute the specific substances to others who are licensed by this state to conduct research or chemical analysis with the schedule 1 substances.

(e) Conducting research with a controlled substance listed in schedules 2 to 5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity who is licensed in this state to conduct research with the controlled substances listed in schedules 2 to 5 may also participate in all of the following activities:

(i) Conduct chemical analysis with the specific substances listed in those schedules.

(ii) Manufacture the specific substances if, and to the extent that, the manufacture of the specific controlled substances is set forth in a statement filed with the application for licensure.

(iii) Distribute the specific substances to others who are licensed in this state to conduct research, chemical analysis, or instructional activity with the substances.

(iv) Conduct instructional activities with the specific substances.

(f) Conducting instructional activities with a specific controlled substance listed in schedules 2 to 5.

(g) Conducting chemical analysis with a controlled substance listed in any schedule An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to conduct chemical analysis with all controlled substances may manufacture the substances for analytical or instructional purposes, distribute the substances to others who are licensed to conduct chemical analysis, instructional activity or research with the substances, and conduct instructional activities with the substances.

(h) A pharmacy stocking patient medication in an automated device located at an affiliated hospital location pursuant to section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in section 20109 of the code, MCL 333.20109. The pharmacy responsible for the device shall obtain an additional controlled substance license for each location. If substances are stored at a health facility without an onsite pharmacy or an automated device stocked by a pharmacy, a designated prescriber shall obtain a controlled substance license.

(4) An applicant shall obtain a separate controlled substance license for each practitioner license issued under article 15 of the code, MCL 333.16101 to 333.18838. The controlled substance license must be renewed when the article 15 license is renewed and the controlled substance license is renewed for an equal number of years as the article 15 license.

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with his or her application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed research.

(b) The protocol and description of the nature of the proposed research that is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to the provisions of 21 CFR 1301.18.

(c) A list of the controlled substances and doses to be used.

(6) An applicant who intends to conduct instructional activity involving controlled substances shall submit all of the following information with his or her application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed instructional activity.

(b) A course outline for the proposed instructional activity.

(c) A list of the controlled substances and doses to be used.

(7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with his or her application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed chemical analysis.

(b) The protocol and description of the nature of the chemical analysis that is filed and approved by the FDA and the DEA pursuant to the provisions of 21 CFR 1301.18.

(c) A list of the controlled substances and doses to be used.

(8) A prescriber or practitioner who is licensed in this state to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations is not required to obtain a separate controlled substance license for each additional physical location of the business or professional practice if the prescriber or practitioner only prescribes controlled substances at each additional physical location of the business or professional practice.

(9) A pharmacist shall maintain 1 controlled substance license in this state to dispense from any licensed pharmacy in this state.

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

Rule 35. (1) An individual who is applying for a controlled substance license or who is licensed to prescribe or dispense controlled substances pursuant to section 7303 of the code, MCL 333.7303, shall complete a 1-time training in opioids and controlled substances awareness that meets the following standards:

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

(i) Use of opioids and other controlled substances.

(ii) Integration of treatments.

(iii) Alternative treatments for pain management.

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

(v) The stigma of addiction.

(vi) Utilizing the MAPS.

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

(viii) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.

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

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

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

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

(iii) Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the code, MCL 333.16101 to 333.18838.

(iv) Training obtained in an educational program that has been approved by a board established under article 15 of the code, MCL 333.16101 to 333.18838, for initial licensure or registration, or by a college or university.

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) A prescriber or dispenser shall ~~not~~ delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with subrules (1) and (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, an individual shall provide an acceptable proof of completion of training, including either of the following:

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

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

(4) An individual who has been issued a controlled substance license pursuant to section 7303 of the code, MCL 333.7303, shall complete the controlled substance training required by subrule (1) of this rule as follows:

(a) A licensee who is renewing his or her controlled substance license shall complete the controlled substance training by the end of the first renewal cycle that begins after January 4, 2019.

(b) Other than a license renewal under subdivision (a) of this subrule, beginning September 1, 2019, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training.

(5) Beginning December 31, 2021, an individual, other than a physician's assistant, who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as allowed by the code, shall complete the controlled substance training required by subrule (1) of this rule.

(6) An individual who is licensed under section 7303 of the code, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals is exempt from this rule.

R 338.3137 Eliminate drug treatment program prescriber license requirement.

Rule 37. The drug treatment program prescriber license is eliminated.

PART 4. SECURITY

R 338.3141 Thefts and diversions.

Rule 41. (1) An applicant or licensee shall provide effective controls against theft and diversion of controlled substances.

(2) A licensee shall confirm that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Rules Committee has asked that the Board address whether the one day notice requirement should be added, consistent with the DEA.Within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, a licensee shall notify the department of the suspected theft or significant loss of a controlled substance and submit a copy of the DEA theft and loss report form 106, or equivalent document, to the department, whether or not the controlled substance is recovered or the responsible person is identified and action is taken against him or her, and whether or not it is also reported to the DEA.

(4) A licensee shall use all of the following criteria to determine if the loss in subrule (3) of this rule is significant:

(a) The quantity of the controlled substance lost in relation to the type of business.

(b) The specific controlled substance lost.

(c) Whether the loss of the controlled substance can be associated with access to the controlled substance by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substance.

(d) A pattern of loss over a specific time period, whether the loss appears to be random, and the results of efforts taken to resolve the loss.

(e) Whether the specific controlled substance is a likely candidate for diversion.

(f) Local trends and other indicators of the diversion potential of the missing controlled substance.

R 338.3143 Storage of controlled substances.

Rule 43. (1) A licensee shall store controlled substances that are listed in schedule 1 in a securely locked, substantially constructed cabinet that is anchored to a wall or the floor.

(2) A licensee shall store controlled substances that are listed in schedules 2, 3, 4, and 5 in a securely locked, substantially constructed cabinet, room, or cart. However, in a pharmacy, the controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

R 338.3145 Employees; disqualification.

Rule 45. (1) An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity who is licensed by the department pursuant to section 7303 of the code, MCL 333.7303 or section 17748 of the code, MCL 333.17748, shall not employ or utilize, with or without compensation, or allow the following individuals access to controlled substances:

(a) An individual who the licensee knows, or should reasonably know, to be a substance abuser as defined in section 16106a of the code, MCL 333.16106a. This subdivision does not apply to a licensee enrolled in the health professional recovery program under a current monitoring agreement.

(b) An individual whose controlled substance license is suspended, revoked, or denied.

(c) An individual whose license issued by this state or another state is under suspension or revoked for a violation that involves controlled substances.

(d) An individual who has been convicted of a crime that involves controlled substances and who is currently under sentence for that conviction.

(2) A licensee shall not delegate, pursuant to section 16215 of the code, MCL 333.16215, to a licensed or unlicensed individual unless the delegation complies with this rule.

PART 5. RECORDS

R 338.3151 Inventories.

Rule 51. (1) An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity licensed to manufacture, distribute, prescribe, or dispense controlled substances shall annually perform and maintain a complete and accurate inventory of all stocks of controlled substances in the possession and control of the licensee.

(2) The inventory must contain a complete and accurate record of all controlled substances in the possession or control of the licensee on the date the inventory is taken as follows:

(a) If the substance is listed in schedule 1 or 2, then the licensee shall make an exact count or measure of the contents.

(b) If the substance is listed in schedule 3, 4, or 5, then the licensee shall make an estimated count or measure of the contents, but if the container holds more than 1,000 dosage units, then the licensee shall make an accurate account of the contents.

(3) A licensee shall make a separate inventory for each licensed location on the date that he or she first engages in the activity covered by his or her license, including a change of a pharmacist in charge. The beginning inventory record for a licensed location shall be kept at the licensed location and a copy shall be forwarded to the department upon request.

(4) A licensee shall indicate on the inventory record whether the inventory was taken at the opening or closing of the day that the inventory is taken.

(5) A licensee shall maintain the inventory in a written, typewritten, or printed form at the licensed location. The inventory taken by use of an oral recording device must be promptly transcribed.

(6) A licensee shall sign and date the inventory record.

(7) A licensee's printed name, address, and DEA number shall be recorded on the inventory.

(8) Schedule 2 drugs must be separated on the inventory from all other drugs.

(9) A licensee that is open for 24 hours shall indicate the time that the inventory was taken.

(10) On the effective date of the addition of a controlled substance to a schedule, which substance was not previously listed in any schedule, a licensee who possesses the substance shall take an inventory of all stocks of the substance on hand and incorporate it in the current inventory. Thereafter, the substance shall be included in each inventory taken.

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.

Rule 53. For 2 years, a licensee shall maintain in the pharmacy responsible for the automated device, for review by the department, an agency, or the board, all records for controlled substances, including invoices, acquisition records, and sales receipts, as follows:

(a) A licensee may keep acquisition records, except for executed or voided DEA 222 order forms, in an electronic form at a central location with notice to the department.

(b) A licensee shall maintain invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 in a separate file from invoices and other acquisition records of controlled substances listed in schedules 3, 4, and 5. The information must be readily retrievable from the ordinary acquisition records maintained by the dispenser.

(c) A licensee shall retain sales receipts for 90 days in electronic or paper form.

(d) A licensee shall initial or electronically initial the invoice and indicate the date that the controlled substances are received.

(e) A licensee shall keep a record, which may be electronic, of all controlled substances dispensed by him or her.

(f) A licensee that prescribes controlled substances shall keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber:

(i) Name of the patient.

(ii) Name and strength of the controlled substance.

(iii) Quantity of the controlled substance.

(iv) Date the controlled substance was dispensed or administered.

(v) Name of the individual who dispensed or administered the controlled substance.

(g) Except in medical institutions, a licensee shall sequentially number and maintain in chronological order the patients' original prescriptions as follows:

(i) A licensee shall maintain a separate file for dispensed substances listed in schedule 2.

(ii) A licensee shall maintain a separate file for dispensed substances listed in schedules 3, 4, and 5.

(h) The licensee shall keep the original prescription record on site for 5 years from the last date of dispensing. However, after 2 years from the last date of dispensing, if an electronic duplicate is made of the original paper prescription, which becomes the original prescription, the original prescription may be destroyed.

(i) A licensee shall maintain records of controlled substances distributed to another licensee, which shall include all of the following information and be maintained in the appropriate file described in subdivision (b) of this rule or in a separate record that is available for inspection:

(i) Name, address, and DEA number of receiver.

(ii) Name, address, and DEA number of supplier.

(iii) Name and quantity of the controlled substances distributed.

(iv) Date the controlled substances were distributed.

(j) A DEA 222 order form must be used for schedule 2 drugs.

(k) Except for controlled substance prescriptions pursuant to subdivision (h) of this rule, a licensee shall maintain controlled substances records for 2 years.

R 338.3153a Medication orders for patients in medical institutions.

Rule 53a. (1) A licensee shall include all of the following information in a prescription for controlled substance medications to be dispensed for administration to an inpatient in a medical institution:

(a) The patient's name.

(b) The prescriber's name, address, and DEA number. In place of including the address and DEA number on each medication order, the pharmacy may maintain a separate list of prescribers. The list must contain the prescriber's name, address, and DEA number.

(c) The prescriber's signature.

(d) The name, dose, and frequency of administration of the medication.

(e) The date of the medication order.

(2) If alternative therapy has been evaluated and the immediate administration of a controlled substance, including a schedule 2 medication, is necessary for the proper treatment of a patient, then a pharmacist may dispense the controlled substance for administration to the inpatient if all of the following conditions are satisfied:

(a) The oral order of the prescriber is committed to a written or electronic order in the patient chart by a nurse licensed under part 172 of the code, MCL 333.17201 to 333.17242, a physician's assistant licensed under part 170 of the code, MCL 333.17001 to 333.17097, or part 175 of the code, MCL 333.17501 to 333.17556, or a pharmacist licensed under part 177 of the code, MCL 333.17701 to 333.17780, who has communicated directly with the prescriber.

(b) The order states the name of the prescriber and the name of the nurse, physician's assistant, or pharmacist who received the verbal order.

(c) The order is forwarded to the pharmacy.

(d) The prescriber signs the original order at the next visit or within 7 days.

(3) A licensee shall preserve an original order for a period of 5 years from the patient discharge date and the original order must be readily retrievable. After 2 years, a licensee may make an electronic duplicate of the original order which becomes the original order. If a licensee maintains patient records electronically, then a printed copy-must be immediately available for a current inpatient and within 48 hours upon request of an authorized agent of the board for any patient of the previous 5 years.

R 338.3154 Medication records in medical institutions.

Rule 54. (1) A patient's chart shall constitute a record of medications ordered for, and actually administered to, a patient of medical institutions.

(2) Medication records are required for all controlled substances listed in schedules 2, 3, 4, and 5. At a minimum, these records must include all of the following information:

(a) The number of doses of controlled substances purchased.

(b) The number of doses dispensed to individual patients or distributed to nursing stations or both.

(c) The number of doses administered.

(d) The number of doses dispensed, but not administered, to the patient.

(3) If the controlled substance is not dispensed to an individual patient, all of the following provisions must be complied with:

(a) Medication records for those controlled substances in schedules 2, 3, 4, and 5 must be maintained.

(b) Distribution of a controlled substance to a nursing unit may not be more than 25 doses per container.

(c) A distribution record for each multiple of 25 doses must be used to account for delivery to a nursing unit. The record must include all of the following information:

(i) The name and dose of the controlled substance.

(ii) The quantity of the substance.

(iii) The date of delivery.

(iv) The location of the nursing unit.

(v) The name of the distributing pharmacy and address if a different location from the medical institution.

(vi) Name of distributing pharmacist.

(vii) The name of the individual on the nursing unit who receives the substance.

(d) A proof of use record must be maintained to account for all doses of an administered substance. The record must include all of the following:

(i) The name of the substance.

(ii) The dose administered.

(iii) The date and time a dose was administered.

(iv) The name of the patient.

(v) The signature of the individual who administered the dose.

(e) Subrule 3 of this rule does not apply to automated devices.

(4) A controlled substance that is maintained at a nursing unit must be stored in a securely locked cabinet or medication cart that is accessible only to an individual who is responsible for the administration or distribution of the medication.

(5) If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:

(a) The name and address of the pharmacy or facility responsible for the operation of the automated device.

(b) The manufacturer, serial number, and model number of the automated device.

(c) The location of the automated device.

(d) The contents of the automated device.

(e) The quality assurance policy and procedure to determine continued appropriate use and performance of the automated device that includes all of the following quality assurance documentation for the use and performance of the automated device:

(i) Use of monitors that alert the user when the wrong medication is filled or removed for administration to a patient.

(ii) Use of security monitors that include an alert for unauthorized access, patients not in the system, system security breaches, and controlled substance audits.

(iii) Corrective measures to address issues and errors identified in the internal quality assurance program.

(f) The policy and procedure for system operation that includes all of the following:

(i) Safety.

(ii) Security systems and procedures that include prevention of unauthorized access or use and comply with federal and state regulations.

(iii) Accuracy.

(iv) Patient confidentiality.

(v) Access.

(vi) Type of controlled substances.

(vii) Data retention or archival.

(viii) Definitions.

(ix) Downtime procedures.

(x) Emergency procedures.

(xi) Operator inspections.

(xii) Installation requirements.

(xiii) Maintenance.

(xiv) Medication security.

(xv) Medication inventory.

(xvi) Staff education and training.

(xvii) System set-up and malfunction.

(xviii) List of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

(xix) The use of the automated device that includes a requirement that a pharmacist review a prescription or medication order before system profiling or removal of any medication from the automated device for immediate patient administration, except in the following situations where a pharmacist shall review the orders and authorize any further dispensing within 48 hours:

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

(B) The system is being used in place of an emergency kit under R 338.486(4)(c).

(C) The system is being accessed to remove medication required to treat the emergent needs of a patient under 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.

(g) The automated device must maintain transaction data that includes all activity regarding access to the contents of the automated device.

(h) The pharmacy responsible for the automated device shall maintain records related to access to the automated device. The records must be readily retrievable and must include all of the following information:

(i) The unique identity of the device.

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

(iii) The type of transaction.

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

(v) The name of the patient.

(vi) The identification of the pharmacist checking for the accuracy of the medications to be stocked or restocked in the automated device.

(vii) Any other information the pharmacist considers necessary.

(i) For medication removed from the automated device for on-site patient administration, the automated device must document all of the following information:

(i) The name of the patient.

(ii) The date and time medication was removed from the automated device.

(iii) The name, initials, or other unique identifier of the individual removing the drug.

(iv) The name, strength, and dosage form of the drug. The documentation may be on paper or electronic medium.

(j) If the pharmacist delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another a board-approved error prevention technology.

(k) The automated device must provide a mechanism for securing and accounting for controlled substances removed from the automated device return bin. Controlled substances may not be returned directly to the automated device for immediate reissue or reuse. Controlled substances removed from the automated device may not be reused or reissued, except as indicated in R 338.486(7).

(l) The automated device must provide a mechanism for securing and accounting for wasted or discarded medications.

(6) An individual who is responsible for administering a controlled substance or a portion thereof shall record the quantity, disposition and an explanation of the destruction of the controlled substance on the proper accountability record. If the institution has a policy that reflects current practice standards and delineates the method of destruction, an explanation would only be required if policy was not followed.

PART 6. DISPENSING AND ADMINISTERING CONTROLLED SUBSTANCE PRESCRIPTIONS

R 338.3161 Controlled substance prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance must be dated and signed by the prescriber, when issued, and contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's DEA registration number, preprinted, stamped, typed, or manually printed name, address, ~~telephone number or pager number,~~ and professional designation.

(c) The drug name, strength, and dosage form.

(d) The quantity prescribed. For a paper prescription received in writing, the prescription must contain the quantity in both written and numerical terms. A paper prescription must contain preprinted numbers representative of the quantity next to a box or line that the prescriber may check.
(e) The directions for use.
(f) If the prescription is for an animal, then the species of the animal and the full name and address of the owner.
(2) A written prescription for a controlled substance in schedules 2 to 5 shall be written legibly with ink or an indelible pencil or prepared using a printer and signed by the prescriber.
(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, but, pursuant to the code, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the code.
(4) If the controlled substance prescription or order in a medical institution is issued pursuant to delegation, then the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee shall be on the written prescription. In medical facilities, orders must contain the signatures of the delegatee and the printed name of the delegating prescriber.
(5) A prescriber shall not issue a prescription to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.
(6) The telephone number or pager number if the prescription must be stored electronically.

R 338.3161a. Exception to bona fide prescriber-patient relationship; alternative requirements.
Rule 61a. (1) A bona fide prescriber-patient relationship is required before a licensed prescriber may prescribe a controlled substance listed in schedules 2 to 5.
(2) Pursuant to Section 16204e of the code, MCL 333.16204e, a licensed prescriber may prescribe a controlled substance listed in schedules 2 to 5 without first establishing the bona fide prescriber-patient relationship required under Section 7303a of the code, MCL 333.7303a, in the following situations:
(a) The prescriber is providing on-call coverage or cross-coverage for another prescriber who is not available and has established a bona fide prescriber-patient relationship with the patient for whom the on-call or covering prescriber is prescribing a controlled substance, the prescriber, or an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, reviews the patient's relevant medical or clinical records, medical history, and any change in medical condition, and provides documentation in the patient's medical record pursuant to medically accepted standards of care.
(b) The prescriber is following or modifying the orders of a prescriber who has established a bona fide prescriber-patient relationship with a hospital in-patient or nursing care facility resident and provides documentation in the patient's medical record pursuant to medically accepted standards of care.

(c) The prescriber is prescribing for a patient that has been admitted to a licensed nursing care facility, completes the tasks identified in subrule (2)(a) and (2)(b) of this rule in compliance with R 325.45377, as applicable, and provides documentation in the patient's medical record pursuant to medically accepted standards of care.

(d) The prescriber is prescribing for a patient for whom the tasks listed in subrule (2)(a) and (2)(b) of this rule have been performed by an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, and the prescriber provides documentation in the patient's medical record pursuant to medically accepted standards of care.

(e) The prescriber is treating a patient in a medical emergency. For purposes of this subdivision, "medical emergency" means a situation that, in the prescriber's good-faith professional judgment, creates an immediate threat of serious risk to the life or health of the patient for whom the controlled substance prescription is being prescribed.

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

Rule 62. (1) Except for a remote pharmacy, which is regulated by section 17742a of the code, MCL 333.17742a, and which allows a qualified pharmacy technician to assist in the dispensing process while being overseen by a pharmacist through the use of a surveillance system and telepharmacy system, a controlled substance shall be dispensed by a pharmacist or a pharmacy intern in the presence, and under the personal charge of a pharmacist.

(2) A pharmacist shall require positive identification of individuals to whom controlled substances are dispensed or delivered when the individual is not known to the pharmacist or pharmacy employees except when positive identification is not available and a pharmacist, who in exercising his or her professional judgment, determines that a delay in dispensing the controlled substance may be detrimental to a patient.

(3) Subrule (2) of this rule does not exempt a pharmacist from the requirement to submit a patient identifier to the electronic system for monitoring controlled substances.

(4) The dispensing pharmacist and pharmacy are both responsible for complying with this rule.

(5) A pharmacist may dispense a controlled substance that is listed in schedules 3 to 5 and that is a prescription drug pursuant to the provisions of the FDCA of 1991, 21 USC 353, only pursuant to a prescription on a prescription form, an oral prescription of a practitioner, or a prescription that is electronically transmitted pursuant to R 338.3162a and that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained pursuant to an oral order.

(6) In addition to the requirements in section 17744 of the code, MCL 333.17744, if a prescriber's agent under delegation transmits an oral prescription for a controlled substance to a pharmacy all of the following shall be recorded on the prescription generated at the pharmacy:

(a) The information required by R 338.3161.

(b) The transmitting agent's identity.

(c) The individual who received the prescription at the pharmacy.

(7) Only a prescription that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.

R 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Rule 62a. (1) Until the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription if all of the following conditions are satisfied:

(a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient.

(b) The electronically transmitted prescription includes all of the following information:

(i) The name and address of the prescriber.

(ii) An electronic signature or other board-approved means of ensuring prescription validity.

(iii) The prescriber's telephone number for verbal confirmation of the order.

(iv) The time and date of the electronic transmission.

(v) The name of the pharmacy intended to receive the electronic transmission.

(vi) Unless otherwise authorized under section 17754(1)(b) of the code, MCL 333.17754, the full name of the patient for whom the prescription is issued.

(vii) All other information that must be contained in a prescription under R 338.3161.

(c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

(d) All requirements in section 17754 of the code, MCL 333.17754, are met.

(2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription.

(3) Effective the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, prescribers shall, unless an exception under section 17754a of the Code, MCL 333.17754a, applies, electronically transmit a prescription for a controlled substance consistent with both of the following requirements:

(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.

(b) All the requirements in R 338.3161 are met.

(4) A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy either of the following requirements:

(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the federal Centers for Medicare and Medicaid Services.

(b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and the prescriber meets 1 of the following:

(i) The prescription is dispensed by a dispensing prescriber.

(ii) The prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber.

(iii) The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following:

(A) Prescribing fewer than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the Federal Centers for Medicare and Medicaid Services waiver for electronic transmission of prescriptions for controlled substances, whichever is more.

(B) Intention to cease practice within the next twelve months.

(C) Limited practice due to an illness or other unforeseen event.

(iv) The prescriber issues prescriptions from a non-profit charitable medical clinic.

(5) A waiver is valid for 2 years and is applicable to the specific circumstances included in the application. A waiver may be renewed by application to the department.

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

Rule 62b. (1) Except as otherwise exempt under section 7333a of the code, MCL 333.7333a, a pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 of the code, MCL 333.17701 to 333.17780, who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a scheduled 2 to 5 controlled substance that has been dispensed:

(a) The patient identifier identification number. For purposes of this subdivision, all of the following apply:

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

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

(iii) If the medication being dispensed is for an animal, the patient identification number applies to the animal's owner, the client, that meets the requirements of R 338.3102(1)(f)(iv). If the animal's owner cannot be identified, zeroes must be entered as the identification number.

(b) The patient's name; client's name, including first name, middle name, or middle initial, if available; and last name.

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

(d) The patient's or client's phone number.

(e) The patient's or client's gender.

(f) The patient's or client's date of birth.

(g) The species code, as specified by ASAP.

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

(i) The NDC of the controlled substance dispensed.

(j) The date of issue of the prescription.

(k) The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

(o) The prescription number assigned by the dispenser.

(p) The prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription.

(q) The prescription payment type. Cash discount cards are considered cash transactions.

(r) The electronic prescription reference number, if applicable.

(s) The patient's or client's location code when receiving pharmacy services, as specified by ASAP.

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

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

(3) As used in this rule, R 338.3162c, and R 338.3162d, the term "dispense" or "dispensing" means the preparation, compounding, packaging, or labeling of a controlled substance along with delivery of the controlled substance pursuant to a prescription or other authorization issued by a prescriber, and does not include the acts of prescribing a controlled substance or administering a controlled substance directly to a patient.

(4) As used in this rule, the term "patient" refers to an individual, not an animal.

R 338.3162c Format for electronic transmission of data to electronic system for monitoring; waiver.

Rule 62c. (1) A pharmacist, dispensing prescriber, or veterinarian who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 shall transmit the data, as specified under R 338.3162b by electronic media or other means as approved by the department or the department's contractor.

(2) The data must be transmitted in the format established by the ASAP 4.1 Standard for Prescription Drug Monitoring Programs.

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and who does not have an automated record-keeping system capable of producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request shall be made in writing to the department.

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if he or she demonstrates an inability to report as required by R 338.3162b and he or she agrees in writing to report the data to the department or the department's contractor by submitting a completed MAPS claim form as defined in R 338.3102(1)(c) or transmitting data via an internet web portal that is provided by the department or the department's contractor for this purpose.

R 338.3162d Required reporting of prescription data; error reporting.

Rule 62d. (1) A pharmacist, pharmacy, dispensing prescriber, or veterinarian shall report all scheduled 2 to 5 controlled substances dispensed.

(2) The licensee shall forward the data required by R 338.3162b by on-line transmission, computer diskette, compact disk, or other approved medium, as specified in R 338.3162c to the department or the department's contractor, on a daily basis, by the end of the next business day and include the data for all controlled substances dispensed since the previous transmission or report.

(3) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, shall mail or deliver the information to a location specified by the department or the department's contractor not later than 7 calendar days after the date that the controlled substance has been dispensed, and include the data for all controlled substances dispensed since the previous transmission or report.

(4) The department or the department's contractor shall notify a pharmacist, pharmacy, dispensing prescriber, or veterinarian of an error in data reporting. Upon receiving notification of an error in data reporting, a pharmacist, pharmacy, dispensing prescriber, or veterinarian shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 7 calendar days of being notified of the error.

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as required, is subject to the penalty provisions in section 16221, 17741, or 17768 of the code, MCL 333.16221, 333.17741, or 333.17768, in article 15 of the code, MCL 333.16101 to 333.18838.

R 338.3163 Individual with substance use disorder; prescribing, dispensing, and administering controlled substance.

Rule 63. (1) A practitioner within his or her scope of practice, may either prescribe, dispense, or administer a controlled substance to an individual with substance use disorder for the purpose of maintenance or detoxification treatment pursuant to any of the following situations:

(a) A practitioner acting pursuant to federal law or regulations to conduct the drug treatment of an individual with substance use disorder may prescribe, dispense, and administer a controlled substance for the purpose of legitimate treatment of the individual with substance use disorder. A prescription may only be issued for a schedule 3 through 5 substance.

(b) A practitioner may administer or dispense a controlled substance approved by the FDA specifically for use in maintenance or detoxification treatment directly to an individual with substance use disorder who is participating in a program.

(c) A practitioner may administer a controlled substance approved by the FDA specifically for use in maintenance or detoxification treatment directly to an individual with substance use disorder who is experiencing acute withdrawal symptoms and administration of a controlled substance is necessary while the practitioner is arranging referral for treatment. The following requirements must be followed:

(i) Not more than 1 day's supply of medication may be administered or directly dispensed to the individual with drug addiction or dependence.

(ii) The emergency treatment may be carried out for not more than 3 consecutive days and may not be renewed or extended.

(2) Notwithstanding subrule (1) of this rule, a practitioner within the scope of his or her practice, may administer or dispense a controlled substance in a hospital or similar setting to an individual with substance use disorder consistent with both of the following:

(a) The controlled substance is administered or dispensed to continue maintenance or detoxification treatment as an adjunct to medical or surgical treatment of conditions other than addiction.

(b) The controlled substance is administered or dispensed to relieve intractable pain for which no relief or cure is possible, or none has been found after reasonable efforts.

(3) As use in this rule:

(a) “Practitioner” means the term defined in section 7109 of the code, MCL 333.7109.

(b) “Program” means the term defined in section 260 of the mental health code, 1974 PA 258, MCL 330.1260.

(c) “Substance use disorder” means that term as defined in section 100d of the mental health code, 1974 PA 258, MCL 330.1100d.

R 338.3164 Emergency dispensing of schedule 2 substances; oral prescriptions.

Rule 64. A pharmacist may dispense a controlled substance listed in schedule 2 in an emergency in which all of the following conditions are met:

(a) The prescriber advises the pharmacist of all of the following:

(i) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(ii) Appropriate alternative treatment is not available, including administration of a drug that is not a controlled substance under schedule 2.

(iii) It is not reasonably possible for the prescriber to provide a written prescription to be presented to the dispenser before the dispensing.

(iv) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period and pursuant to a written prescription.

(b) The pharmacist shall immediately put the prescription in writing, which contains the information that must be contained in a prescription under R 338.3161, except for the prescriber's signature.

(c) If the prescriber is not known to the pharmacist, then the pharmacist shall make a reasonable effort to determine that the oral authorization came from a prescriber by returning the prescriber's call, using the telephone number listed in the telephone directory, and other good faith efforts to ensure the prescriber's identity.

R 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Rule 65. (1) Within 7 days after authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall comply with all of the following:

(a) The prescriber shall deliver to the dispensing pharmacist a written prescription or electronically transmit the prescription pursuant to R 338.3162a.

(b) The prescriber shall include on the prescription both "Authorization for Emergency Dispensing" and the date of the oral order.

(2) A pharmacist that has dispensed a prescription on an emergency oral prescription shall comply with all of the following:

(a) The dispensing pharmacist shall reduce the oral prescription to writing.

(b) Upon receipt of the prescription, the dispensing pharmacist shall attach the prescription to the oral order which was earlier reduced to writing.

(c) The pharmacy shall notify the department if the prescriber fails to deliver to him or her either a written prescription or a prescription transmitted electronically.

(3) The failure of the pharmacy to notify the department if the prescriber fails to deliver a prescription pursuant to subrule (1) of this rule voids the authority conferred by this rule.

R 338.3166 Partial dispensing of controlled substances.

Rule 66. (1) A pharmacist may partially dispense a controlled substance listed in schedule 2 in conformance with the following:

(a) The pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription.

(b) The pharmacist makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record.

(c) The pharmacist may dispense the remainder of the prescription within 72 hours after the first partial dispensing.

(d) If the remainder of the prescription is not or cannot be dispensed within the 72 hours, the pharmacist shall notify the prescriber.

(e) The pharmacist shall not dispense any additional quantity beyond 72 hours without a new prescription.

(f) The pharmacy must have the balance of the prescription ready for dispensing before the 72-hour limit, but the patient is not required to pick up the balance of the prescription within that 72-hour limit.

(2) A pharmacist may partially dispense a prescription for a controlled substance in schedule 2 at the request of the patient or the prescribing practitioner in conformance with the following:

(a) The prescription is written and filled pursuant to the CSA and DEA regulations and state law.

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(c) The remaining portions of a partially filled prescription in schedule 2, if filled, shall be filled not later than 30 days after the date on which the prescription was written.

(d) For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(i) Date of the partial filling.

(ii) Quantity dispensed.

(iii) Remaining quantity that may be dispensed.

(iv) Identification of the dispensing pharmacist.

(3) A pharmacist may partially dispense, including individual dosage units, a prescription for a schedule 2 controlled substance that is written for a patient in a long-term care facility or for a patient with a medical diagnosis that documents a terminal illness in conformance with all of the following:

(a) For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(i) Date of the partial filling.

(ii) Quantity dispensed.

(iii) Remaining quantity authorized to be dispensed.

(iv) Identification of the dispensing pharmacist.

(b) The total quantity of schedule 2 controlled substances dispensed in all partial fillings may not be more than the total quantity prescribed.

(c) Prescriptions are valid for a period of not more than 60 days from the issue date unless terminated at an earlier date by the discontinuance of medication.

(d) A pharmacist shall record on the prescription whether the patient is terminally ill or is a long-term care facility patient.

(4) A pharmacy may partially fill a prescription for a schedule 3, 4, or 5 controlled substance if all of the following provisions are met:

(a) Each partial filling is recorded in the same manner as a refilling.

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(c) No dispensing occurs after 6 months from the date the prescription was issued for schedules 3, 4, and 5.

R 338.3167 Dispensing schedule 5 substances without prescriptions.

Rule 67. (1) A pharmacist may, without a prescription, dispense a controlled substance listed in schedule 5 that is not a prescription medication as determined under the FDCA, 21 USC 301 to 392, if all of the following provisions are met:

(a) The dispensing pharmacist determines the controlled substance is intended to be used for a medical purpose.

(b) Not more than 240 cc, 8 ounces, or 48 solid doses of a substance containing opium or more than 120 cc, 4 ounces, or 24 solid doses of any other substance listed in schedule 5 are distributed at retail to the same purchaser in any single 48-hour period.

(c) The purchaser is not younger than 18 years of age.

(d) The dispensing pharmacist requires a purchaser, not known to the pharmacist, to furnish suitable identification, including proof of age where appropriate.

(2) If a pharmacist dispenses a controlled substance listed in schedule 5 without a prescription, then he or she shall affix to the container in which the substance is dispensed a label that shows the date, his or her name, and the name and address of the place of practice where the substance is dispensed.

(3) The pharmacist shall maintain a record of the dispensing without a prescription of controlled substances listed in schedule 5 with the following requirements:

(a) The record must be kept for 5 years from the date of dispensing. After 2 years, an electronic duplicate of the original order may be made which becomes the original record.

(b) The record must be immediately retrievable and may be maintained in the same manner as required for schedule 5 prescription medication.

(c) The record must contain all of the following information:

(i) The name and address of the patient.

(ii) The name and address of the purchaser if different from the patient.

(iii) The name and quantity of substance purchased.

(iv) The date purchased.

(v) The name or initials of the pharmacist or pharmacy intern who dispensed the substance.

(vi) The medical purpose for which the medication is being used as determined by the pharmacist.

R 338.3168 Refilling of prescriptions.

Rule 68. (1) A prescription for a controlled substance listed in schedule 2 may not be refilled.

(2) A prescription for a controlled substance listed in schedules 3 and 4 may not be refilled more than 6 months after the prescription's date of issuance and may not be refilled more than 5 times. Renewal of the prescription must be consistent with the requirements for original prescriptions.

(3) A prescription for a controlled substance listed in schedule 5 may be refilled only as expressly authorized by the prescriber on the prescription up to 1 year; if no authorization is indicated, then the prescription may not be refilled.

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of his or her professional practice may dispense, ~~or~~ administer, or delegate under direct supervision the administering of a controlled substance listed in schedules 2 to 5.

(2) A veterinarian, in the course of his or her professional practice may dispense, administer, or delegate the administering under direct supervision of a controlled substance listed in schedules 2 to 5 to an animal.

PART 7. DISTRIBUTIONS

R 338.3181 Distributions by dispensers.

Rule 81. (1) A dispenser who is not licensed as a wholesale distributor may distribute a controlled substance to another dispenser for the purpose of general dispensing to his or her patients if all of the following conditions are satisfied:

(a) The receiving dispenser is licensed to dispense the substance.

(b) The distribution is recorded by the distributing dispenser and a receipt record is maintained by the receiving dispenser.

(c) An order form for substances listed in schedules 1 and 2 is used.

(d) The total number of dosage units of all controlled substances distributed by the distributing dispenser during the 12-month period in which the dispenser is licensed is not more than 5% of the total number of all dosage units distributed and dispensed during the 12-month period.

(2) If the dispenser has reason to believe that the total number of dosage units which will be distributed by him or her pursuant to this rule will be more than 5% of the total number of dosage units of all controlled substances distributed and dispensed by him or her during the 12-month period, the dispenser shall obtain a license to distribute controlled substances.

R 338.3183 Distribution to suppliers.

Rule 83. (1) A person who is lawfully in possession of a controlled substance that is listed in any schedule may distribute the substance to the person from whom he or she obtained the substance or to the manufacturer of the substance without obtaining a license to distribute. The person who distributes the substance shall maintain a written record that contains all of the following information:

(a) The date of the distribution.

(b) The name, form, and quantity of the substance.

(c) The name, address, and license number, if any, of the person who makes the distribution.

(d) The name, address, and license number, if known, of the supplier or manufacturer.

(2) In the case of a controlled substance listed in schedules 1 or 2, an order form must be used and maintained as the written record of the distribution.

R 338.3185 Discontinuances and transfers.

Rule 85. A licensee who wants to discontinue or transfer business activities or a professional practice altogether or only with respect to controlled substances shall return his or her DEA registration and any unexecuted order forms in his or her possession to the DEA. The licensee shall return the state controlled substances license to the department. The transfer of the controlled substances is subject to approval by the DEA pursuant to the provisions of 21 CFR 1301.52 and written notification must be provided to the department.

R 338.3186 Use of order forms and invoices.

Rule 86. An order form must be used to distribute schedule 2 substances and an invoice must be used to distribute schedules 3 to 5 substances. The order form may be executed only by a practitioner who is licensed under article 7 of the code, MCL 333.7101 to 333.7545, to prescribe or dispense controlled substances.

~~PART 8. ADMINISTRATIVE AND DISCIPLINARY PROCEDURE~~

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY TECHNICIANS

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(9) 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 16148, 17707, 17731, 17739, 17739a, 17739b, and 17739c, of 1978 PA 368, as amended, MCL 333.16145(3), 333.16148, 333.17703, 333.17707, 333.17731, 333.17739, 333.17339a, 333.17739b, and 17739c and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, and 2011-4, MCL 330.3101, 445.2001, 445.2011, and 445.2030)

R 338.3651, etc of the Michigan Administrative Code is amended as follows:

R 338.36 Definitions.

Rule . (1) As used in these rules:

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

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

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

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning when used in these rules.

R 338.3651 Pharmacy technician licensure; eligibility; examination.

Rule 1. (1) 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 unless the applicant is exempt from filing under any of the following exemptions pursuant to section 17739a(4) of the code, MCL 333.17739a:

(a) A student enrolled in a pharmacy technician program approved by the board under R 338.3655.

(b) A licensee who holds a temporary pharmacy technician license under R 338.3652 and section 17739b of the code, MCL 333.17739b.

(c) A licensee who holds a limited pharmacy technician licensee under section 17739c of the code, MCL 333.17739c.

(2) In addition to meeting the requirements of **the public health code-general rules, and any other administrative rules promulgated under the code, and** section 16174 of the code, MCL 333.16174, an applicant shall comply with all of the following requirements:

(a) 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) Have passed and provided proof to the department of passing any of the following examinations:

(i) 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 has been approved by the board under R 338.3654.

(iii) An employer-based training program examination that has been approved by the board under R 338.3654.

(c) Beginning March 16, 2021, an applicant shall submit proof of having completed **the 1-time** training in identifying victims of human trafficking as required in R 338.3659 **and section 16148 of the code, MCL 333.16148**.

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

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

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

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, of the code, 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 **who has never held a pharmacy technician license in this state, who is licensed in another state, may apply** for licensure by endorsement ~~shall~~ **by** ~~submit~~**submitting** a completed application on a form provided by the department, together with the requisite fee. An applicant who meets the requirements of this rule**, the requirements of the code, the public health code-general rules, any other administrative rules promulgated under the code, as well as all of the following requirements,** 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) 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) Satisfy the requirements in section 16174 of the code, MCL 333.16174.

(c) Hold a pharmacy technician license or registration by examination in another state that is active and in good standing.

(d) Submit proof that the applicant passed 1 of the approved examinations specified in R 338.3651(2)(b).

(e) **Submit** proof of having completed **the 1-time** training in identifying victims of human trafficking as required in R 338.3659 **and section 16148 of the code, MCL 333.16148**..

~~(3) In addition to meeting the requirements of subrules (1) and (2) of this rule, an applicant's license must be verified, on a form provided by the department, by the licensing agency of any state in which the applicant holds a current license or ever held a license as a pharmacy technician. 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.~~ **Discloses each license, registration, or certification in a health profession or specialty issued by any other state, the United States military, the federal government, or another country on the application form.**

R 338.3654 Examination requirements; board approval; approval process.

Rule 4. (1) Except for the PTCB and NHA examinations, a nationally recognized pharmacy technician proficiency certification examination and an employer-based training program proficiency examination must be approved by the board.

(2) An employer-based training program proficiency examination must be offered in association with a specific employer-based training program and cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

(3) An entity that offers a nationally recognized pharmacy technician proficiency certification examination shall submit to the department a completed application on a form provided by the department with proof of current national accreditation in order to be approved by the board. If the examination is nationally accredited, after the department processes the application, it shall be considered approved by the board. If national accreditation is lost, the examination will no longer be approved by the board.

(4) An entity that offers an employer-based training program proficiency examination 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.

(5) An entity that offers an employer-based training program proficiency examination shall submit a modification to a proficiency examination during its approval term to the department on a form provided by the department pursuant to the requirements of this rule.

(6) Beginning July 1, 2022, a nationally recognized certification proficiency examination or employer-based training program proficiency examination approved by the board before July 1, 2022, shall submit an application consistent with this rule for approval.

(7) Beginning July 1, 2022, the board's approval of an examination expires 5 years after the date of approval.

R 338.3655 Approved pharmacy technician programs.

Rule 5. (1) The following pharmacy technician programs are considered board-approved after a completed application on a form provided by the department along with proof of accreditation is submitted to and reviewed by the department:

(a) A pharmacy technician program including an employer-based training program that is accredited by the American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education Pharmacy Technician Accreditation Commission (ASHP/ACPE).

(b) A pharmacy technician program that is offered by an education program that is accredited by the ASHP/ACPE or by an agency accredited by the United States Department of Education.

(2) If either of the following pharmacy technician programs do not meet the requirements in subrule (1) of this rule, the program may apply for board approval by submitting an application to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required in subrule (3) of this rule.

(a) A comprehensive curriculum-based pharmacy technician education and training program conducted by a school that is licensed pursuant to the proprietary schools act, 1943 PA 148, MCL 395.101 to 395.103.

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

(3) The contents of the training programs offered under subrule (2) of this rule must include 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, 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.

(4) The pharmacy technician program shall maintain a record of a student's pharmacy technician training and education, specified in this rule, for 3 years after a student completes or leaves the program, whichever is earlier, that must 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 program and date the student successfully completed the program.

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

(5) A student shall complete a board-approved pharmacy technician program within 2 years of beginning the program in order to maintain his or her exemption from licensure in subrule (6) of this rule, and R 338.3651.

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

(7) Beginning July 1, 2022, a pharmacy technician program that was board approved before July 1, 2022, must reapply and meet the requirements of this rule. Beginning July 1, 2022, the board's approval of a program expires 5 years after the date of approval. After 5 years, upon

review by the department, a pharmacy technician program may be reapproved if it has maintained its accreditation.

(8) If after a program has been approved, the department determines that a program is not meeting the standards of the code or these rules, the department may send written notice to the program stating the areas in the program which are deficient. The program will have 30 days to fix any deficiency and report back to the department. If the deficiencies are not resolved the board may withdraw approval.

(9) Withdrawal of board approval of a program for stated deficiencies which were not remediated does not necessarily make any bona fide student enrolled in the program at the time of withdrawal of approval ineligible for the required licensure examination.

R 338.3657 Relicensure requirements for pharmacy technicians.

Rule 7. **(1)** An applicant for relicensure whose pharmacy technician license has lapsed **in this state** under ~~the provisions of~~ section 16201(3) or (4) of the code, MCL 333.16201, as applicable, may be relicensed by complying with the following requirements:

(a) For a pharmacy technician who has let his or her license lapse **in this state** and who is not currently licensed in another state:	Lapsed 0-3 years	Lapsed more than 3 years
(i) Application and fee: Submit a completed application on a form provided by the department, together with the requisite fee.	√	√
(ii) Good moral character: Establish that he or she is of good moral character as defined **in, and determined** under ~~sections 1 to 7 of~~ 1974 PA 381, MCL 338.41 to 338.47.	√	√
(iii) Submit fingerprints: Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		√
(iv) Continuing education: Submit proof of having completed 20 hours of continuing education specified in R 338.3661(1)(c) that was completed within the 2-year period preceding the date of the application for relicensure. If the continuing education hours submitted with the application are deficient, an applicant shall have 2 years from the date of the application to complete the deficient hours. The application ~~will~~**must** be held, and the license will not be issued until the continuing education requirements have been met.	√	√
(v) Examination: Within 2 years ~~of the period~~ preceding the application for relicensure, pass 1 of the examinations specified in R 338.3651(2)(b)(i) to (iii).		√
(vi) 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.		
(vii) ~~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.~~ **An applicant who is or has ever been licensed, registered, or certified in a health profession or specialty by any other state, the United States military, the federal government, or another country, shall do both of the following:** **(A) Disclose each license, registration, or certification on the application form.** **(B) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which include verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.**	√	√
(b) For a pharmacy technician who has let his or her license lapse in this state, but who holds a current and valid pharmacy technician license in another state:	**Lapsed 0-3 years**	**Lapsed more than 3 years**
(i) Application and fee: Submit a completed application on a form provided by the department, together with the requisite fee.	√	√
(ii) Good moral character: Establish that he or she is of good moral character as defined in, and determined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to 338.47.	√	√
(iii) Submit fingerprints: Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		√
(iv) Continuing education: Submit proof of having completed 20 hours of continuing education specified in R 338.3661(1)(c) that was completed within the 2-year period preceding the date of the application for relicensure. If the continuing education hours submitted with the application are deficient, an applicant shall have 2 years from the date of the application to complete the deficient hours. The application willmust be held, and the license will not be issued until the continuing education requirements have been met.	√	√

(v) Examination: Within 2 years of the period preceding the application for relicensure, pass 1 of the examinations specified in R 338.3651(2)(b)(i) to (iii).		√
(vi) 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.	√	√
(vii) 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. An applicant who is or has ever been licensed, registered, or certified in a health profession or specialty by any other state, the United States military, the federal government, or another country, shall do both of the following: **(A) Disclose each license, registration, or certification on the application form.** **(B) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which include verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.**	√	√

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

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 covers 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 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 March 16, 2016, and for initial licenses issued after March 16, 2021.

R 338.3661 License renewals; continuing education requirements.

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

These rules apply to applications for renewal of a pharmacy technician's license and a special retired volunteer pharmacy technician'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) Submit to the department a completed application ~~for renewal~~ on a form provided by the department together with the requisite fee.

(b) Complete the **1-time** training in identifying victims of human trafficking as required in R 338.3659 **and section 16148 of the code, MCL 333.16148**.

~~(c) Except as otherwise provided in subrule (6) of this rule, comply with 1 of the following:~~

~~(i) Complete a proficiency examination as specified in R 338.3651(2)(b)(i) to (iii).~~

~~(ii) 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, that meet all of the following requirements:~~

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

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

(C) Not less than 5 of the continuing education credits must 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.

(D) Continuing education credit must be earned as follows:

Subjects		Number of continuing education hours required or permitted for each activity
(I)	Pain and symptom management relating to the practice of pharmacy.	Minimum: 1 hour
(II)	Patient safety.	Minimum: 1 hour
(III)	Pharmacy law.	Minimum: 1 hour
(IV)	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. Instruction in each subject is not required.

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

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

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

(c) A program approved by the ASHP/ACPE.

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

(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 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.

(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) If audited, a licensee shall submit to the department a copy of a letter or certificate of completion that includes all of the following:~~

~~(a) The licensee's name.~~

~~(b) The number of hours earned.~~

~~(c) The sponsor name or the name of the organization that approved the program or activity.~~

~~(d) The date on which the program was held or activity completed.~~

~~(6) 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, an applicant shall meet the requirements of this subrule and the requirements in subrules (1)(a) and (b), (3), and (4) of this rule.~~ An applicant for license renewal, who has been licensed for the entire 2-year period preceding the end of the license cycle, shall during the 2 years immediately preceding the application for renewal complete not less than 20 hours of continuing education approved by the board under R 338.3662 as follows:

~~(a)~~**(i)** An applicant for license renewal shall complete 1 hour in pharmacy ethics and jurisprudence.

~~(b)~~**(ii)** An applicant for license renewal shall complete 1 hour in pain and symptom management in the practice of pharmacy that includes, but is not limited to, courses in the following subjects:

~~(i)~~**(A)** Behavior management.

~~(ii)~~**(B)** Psychology of pain.

~~(iii)~~**(C)** Pharmacology.

~~(iv)~~**(D)** Behavior modification.

~~(v)~~**(E)** Stress management.

~~(vi)~~**(F)** Clinical applications as they relate to professional practice.

~~(c)~~**(iii)** An applicant for license renewal shall complete 1 hour in patient safety.

~~(d)~~**(iv)** An applicant for license renewal shall earn no more than 12 hours of continuing education during a 24-hour period.

~~(e)~~**(v) Except for the 1-time training in human trafficking and the implicit bias training, which may be used to comply with both the training requirement and the continuing education requirement in the same renewal period, an applicant for license renewal may not earn continuing education credit for a program or activity that is identical to a program or activity an applicant has already earned credit for during that renewal period.** ~~An applicant for license renewal shall not earn credit for taking the same continuing education course or program twice during 1 renewal period.~~

~~(f)~~**(vi)** An applicant for license renewal shall earn ~~not less than~~**at least** 5 hours of continuing education in live**, synchronous, courses or programs, in-person or virtual, that provide for the opportunity of direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops. Accreditation Council for Pharmacy Education (ACPE) courses designated as live meet this requirement.**

~~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.~~

(2) Submission of an application for renewal shall constitute the applicant's certification of compliance with this rule. The licensee shall retain documentation of meeting the requirements of this rule for a period of 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.

(3) A request for a waiver under section 16205 of the code, MCL 333.16205, must be received by the department for the board's consideration at least 30 days before the last regularly scheduled board meeting before the expiration date of the license. The public notice for the board meetings can be found here: Dentistry (michigan.gov).

(4) Continuing education that is earned during the 60-day grace period may be included up to the date the application for renewal is filed.

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 ASHP/ACPE or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP). • A continuing education sponsoring organization, institution, or individual approved by the ASHP/ACPE. • Another state board of pharmacy. If audited, a licensee shall submit to the department 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 pharmacy practice or administration courses offered for credit in a pharmacy program accredited by the ASHP/ACPE or the CCAPP. If audited, a licensee shall submit to the department an official transcript that reflects	Twelve hours of continuing education will be credited for each academic quarter credit earned and 18 hours will be credited for each academic semester credit earned. No limitation on the number of

	completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	hours earned.
(c)	Participation in a home study program offered through an ASHP/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 to the department 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)	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. If audited, a licensee shall submit to the department 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.	Twenty hours will be earned. A maximum of 20 hours may be earned in each renewal period.
(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 to the department 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.
(f)	Presentation of a continuing education program approved by the board under R	Two hours will be earned for every 50 minutes devoted to

	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 to the department a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.	presenting the program. A maximum of 10 hours may be earned in each renewal period.
(g)	Attendance at a pharmacy-related program, that is approved by the board pursuant to R 338.3663. If audited, a licensee shall submit to the department 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.

R 338.3663 Continuing education **courses and programs;** standards for approval.

Rule 13. ~~(1)~~ A continuing education course or program that is not pre-approved under ~~R 338.3661(2) or~~ 338.3662(a) may be approved by the board **pursuant to the following standards in this rule:** ~~by the course or program sponsor submitting to the department a completed application on a form provided by the department, no later than 70 days before the course or program date, and no later than 70 days before the next regularly scheduled board meeting. A course or program conducted before board consideration and approval shall be denied approval. The application and supporting documentation must include all of the following information:~~

(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~~ before the date the continuing education course or program is conducted for the proposed continuing education to be considered for approval by the board.

(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 338.3662 and must be relevant to health care services, pharmacy operations, or advancement of the licensee's pharmacy education.

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

(i) Availability of adequate records of participation.

(ii) Qualified teaching staff.

(iii) A statement of educational objectives.

(e) Board approval is valid for 3 years from the date of approval.

(f) Except as provided in subdivision (g) of this subrule, any subsequent 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.

(g) The board shall reevaluate an approved continuing education course or program before any changes during the approval term, the title, number of continuing education hours to be awarded to participants, or learning objectives.

(h) 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.

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

~~(a) A course or program schedule that includes all of the following:~~

~~(i) The date of the course or program.~~

~~(ii) The topics to be covered in the course or program.~~

~~(iii) The names of all of the speakers.~~

~~(iv) Break times.~~

~~(b) An explanation of how the course or program is 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 course or program.~~

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

~~(f) A description of how the amount of continuing education credit to be awarded for this course or 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 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 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 course or program approved under subrule (1) of this rule must meet all of the following:~~

~~(a) Be an organized course or program of learning that 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 that demonstrates consistency with the course or program description and reflects the course or program content.~~

~~(d) Be taught in a manner appropriate to the educational content, objectives, and purpose of the course or 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 or program.~~

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

~~(g) Offer educational materials for each continuing education activity that 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 is valid for a 3-year term from the date of the board's approval.~~

~~(5) The board shall reevaluate a course or program before any changes are made during the approval term, including but not limited to, changes to either of the following:~~

~~(a) Instructors and speakers.~~

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

~~(6) All of the following apply regarding changes to a previously approved course or program:~~

~~(a) Subject to subdivision (b) of this rule, all changes to a previously approved course or program must be submitted on required department forms at least 70 days before the date the course or program is offered to participants and at least 70 days before 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, other than those approved under subdivision (b) of this subrule, must not be made to the course or program without prior approval.~~

~~(b) Emergency changes to instructors and speakers that cannot be submitted to the board at least 70 days before the date of the course or program or at least 70 days before the next regularly scheduled board meeting 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.~~

~~(c) 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.~~

~~(7) The provider or sponsor of a course or program shall issue certificates or letters of attendance that include all of the following:~~

~~(a) The name of the sponsor.~~

~~(b) The name of the course or program.~~

~~(c) The name of the attendee.~~

~~(d) The date of the course or program.~~

~~(e) The continuing education approval number 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 awarded.~~

~~(8) The provider or sponsor of a course or program shall maintain records of the information contained in subrule (7) of this rule for 5 years after the course or program is offered to participants.~~

~~(9) 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 338.3665 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, a licensed pharmacy technician may also engage in the following tasks, under the delegation and supervision of a licensed pharmacist:

(a) Reconstituting non-sterile dosage forms consistent with approved labeling provided by the manufacturer of a commercially available product.

(b) Technology-assisted final product verification, which includes all the following:

(i) A second licensed pharmacy technician verifies the work of the first licensed pharmacy technician to perform final product verification.

(ii) The first-licensed pharmacy technician processes a medication order or prescription.

(iii) The first-licensed pharmacy technician processes the medication order or prescription using bar coding or another board-approved error prevention technology.

(iv) A pharmacist verifies the first-licensed pharmacy technician's processing of the medication order or prescription.

(v) The second licensed pharmacy technician technology-assisted final product verification is subject to all of the following requirements:

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

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

(C) The licensed pharmacy technician performing technology-assisted final product verification has not less than 1,000 hours of pharmacy technician work experience in the same kind of pharmacy practice site in which the technology-assisted final product verification is performed while he or she holds a current full pharmacy technician license in this state, not a temporary or limited license.

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

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

(F) The technology enabled verification system must document and electronically record each step of the prescription process including which individuals complete each step.

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

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

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

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