MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
MARCH 2, 2022

The Michigan Board of Pharmacy Rules Committee Work Group met on March 2, 2022. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 9:02 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
Tina Ingraham, Analyst, Licensing Division
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support Technician,
Boards and Committees Section

Public Present: Jessica Adams – Cardinal Health
Farah Jalloul – Michigan Pharmacists Association
Jonathan McLachlan – AllianceRx Walgreens Prime
Grace Sesi, PharmD

RULES DISCUSSION

Ditschman stated that the Central Fill Pharmacies draft was brought back to the Rules Committee as the Department pharmacist had some additional questions.

Pharmacy – Central Fill Pharmacies (A copy of the draft, pursuant to today's discussion, is attached)

Subdivision (1)(b): Ditschman stated that there was a question why there was a change in the term centralized prescription processing to central fill pharmacies when all pharmacies are not using central fill but may be using some type of centralized prescription processing. There was a suggestion to add examples to the definition for clarification.

Mollien stated that if the examples were generic, they should not be added as it would cause the definition to be too broad.

Taylor agreed.

Subdivision (1)(c): Ditschman stated that the exceptions listed seem to be included in the definition in the code.

Mollien stated that record handling is different for a dispensing pharmacy and a central fill pharmacy.

Ditschman read the definition from the statute. She asked if "other functions related to the practice of pharmacy" cover records?

Discussion was held. It was agreed that the point of listing the exceptions was to clarify that these entities are not exempted from the general requirements.

Ditschman suggested deleting the list of exceptions and instead refer to the rules in the general rules that also apply to "record keeping and data entry."

The Rules Committee agreed with the suggested change.

Subdivision (1)(c)(v): Ditschman asked for clarification as to what this subdivision meant.

Discussion was held.

Ditschman suggested using a rule reference, similar to what was being done for (i) through (iv).

The Rules Committee agreed to the suggested change.

Subdivision (1)(g): Ditschman stated that the terms “delivering pharmacist”, “delivering pharmacy”, and “originating pharmacy” were used in the rule. She asked if the term “originating pharmacist” should also be included.

Discussion was held regarding the process a prescription goes through in centralized processing.

Mollien stated that “originating” is just used to indicate where the prescription started, not who started it.

Ditschman asked if the intent is to put the responsibility on the originating pharmacy.

Mollien stated that several pharmacists could be involved at the originating pharmacy, and ultimately the responsibility falls on either the pharmacy or the pharmacist-in-charge.

Adams stated that the way the rule is currently written follows the DEA regulation on controlled substances for central fill.

The Rules Committee agreed not to add originating pharmacist.

Ditschman stated that she would work on language for the rule reference.

Pharmacy – Controlled Substances (A copy of the draft, pursuant to today’s discussion, is attached).

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

Ditschman stated that there are drugs that need further discussion to clarify their schedule.

Salvia: Ditschman stated that this drug is not federally regulated but was listed in the code under MCL 333.7212(1)(v) and (w). Because it is not federally regulated, the Rules Committee must determine if it should be added in the exception section as scheduled in Michigan.

Mollien stated that it could be added back into the rules.

The Rules Committee agreed that it should be scheduled as it was previously listed in the code.

Isomers: Ditschman stated that the federal definition of isomers is narrower than the code.

Mollien stated that it should be listed in the code, using the broader definition.

The Rules Committee agreed.

Hydrocodone containing products (HCPs): Ditschman stated that federally, hydrocodone is scheduled as a 2.

The Rules Committee agreed that they should be listed as schedule 2 in the rule.

Phencyclidine (PCP): Ditschman stated that PCP is listed differently in the code and the federal schedule.

The Rules Committee agreed to follow the federal guidelines.

Tetrahydrocannabinol (THC): Ditschman stated that federal guidelines use a slightly different definition.

The Rules Committee agreed to follow the federal guidelines.

Cannabinoids: Ditschman stated that the definition in the code is broader than the federal schedule.

Mollien stated that the definition could be added. He added that cannabis is defined in the public health code.

The Rules Committee agreed to add the definition from the code.

Pentazocine: Ditschman stated that this is under subdivision (3)(e) as a schedule 4 controlled substance which was the same as the federal guidelines.

Mollien stated that it is scheduled differently in the code, so it should stay in the rule in order to align with the federal guidelines.

R 338.3161 Controlled substance prescriptions.

Subdivision (1)(b): Mollien stated that the prescriber's "telephone number or pager number" could be removed as a requirement for the label. This information is stored electronically and should not hold up the dispensing of a prescription.

Discussion was held.

Mollien will provide Ditschman with language to state that it needs to be stored electronically. The practice in the field is to use the phone number in the system, not on the script, as the script is not always correct.

Hudson stated that the telephone number on the label assists in identifying fraudulent prescriptions. This is a good identifier in investigations as written prescriptions are still used.

The Rules Committee agreed to remove the "telephone number or pager number" language and to take new language, provided by Mollien, to the Board.

Subrule (2): Ditschman asked if this subrule was consistent with the recent statement from the DEA regarding signature requirements being required on prescriptions, regardless of the format of the prescription.

The Rules Committee agreed that it was.

Ditschman asked the Rules Committee if any additional information was necessary in a rule regarding the transfer of initial prescription fills.

Poynter stated that transfers are covered in the code.

Jalloul stated that the MPA refers transfer questions to the DEA.

Discussion was held.

Mollien stated that the rules are consistent with the federal law, therefore nothing additional needs to be added.

The Rules Committee agreed that no additional language was needed regarding transfers of initial prescription fills.

R 338.3141 Thefts and diversions.

Subrule (3): Ditschman asked the Rules Committee if the 15 day requirement should be changed to 1 day, to be consistent with the DEA. Previously, the Department had agreed that it did not need notice pursuant to the 1 day requirement and instead it wanted the information once the investigation was complete.

Taylor stated that using 1 day, in practice, would be a challenge and a distraction from day-to-day operations, on top of the investigation.

Mollien asked if the Department could handle 1 day notices.

Hudson stated that the Department could handle the increase in notifications. He stated that historically, facilities have stated that it is difficult to conduct their own investigation when also having to deal with the investigation from the Department.

Ditschman will discuss with the Board.

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

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

Ditschman stated that the question of how unconventional hours are verified to the Department came up at the last Board meeting. The rules require that the request be made to the Department before the applicant can start accumulating hours, but there is no formal requirement for follow up verification.

Poynter stated that currently, the Department receives a letter. The Internship Affidavit form does not apply to unconventional hours, as it is not always a preceptor providing the supervision.

Mollien asked if a form could be created to verify the unconventional hours.

Ditschman stated that a form could be created but, for clarification to the intern, language should be added to the rule stating that a form needed to be completed.

The Rules Committee agreed that a form should be required, and language added to the rule stating that.

R 338.519 Examinations adoption; passing scores; reexamination.

Ditschman stated that the topic of removing the MPJE from the rules had been brought up at the last Board meeting.

Sesi stated that Idaho and Vermont have both eliminated the requirement from their rules and that Ohio removed it from applicants applying for endorsement who have been actively licensed for more than a year.

Sleiman suggested increasing the pharmacy law requirement for continuing education.

Taylor suggested an attestation stating that the applicant has familiarized themselves with Michigan pharmacy law.

Discussion was held regarding the Board's role in working with NABP to ensure that the questions for the MPJE examination are up to date and correct. Sesi stated that she was scheduled to attend in 2020 and then the pandemic hit so it was cancelled.

Mollien stated that if the examination is not being updated, then it would be appropriate to remove the requirement from the rule. Ditschman explained that the Chairperson appoints someone to assist with the review of the examination.

Jalloul stated that the MPA could work with schools to ensure that pharmacy law is included in their curriculums. She agreed with increasing the pharmacy law requirement for continuing education.

Boutros stated that pharmacy law changes daily and that the application of the law is more important than passing an examination.

The Rules Committee agreed to remove the MPJE requirement for initial licensure as well as for endorsement applicants.

ADJOURNMENT

Ditschman stated that another Rules Committee Work Group meeting is needed.

Ditschman adjourned the meeting at 11:00 a.m.

Prepared by:
Stephanie Wysack, Board Support Technician March 10, 2022
Bureau of Professional Licensing

DEPARTMENT OF ~~COMMUNITY HEALTH~~**LICENSING AND REGULATORY AFFAIRS**

DIRECTOR'S OFFICE

~~CENTRALIZED PRESCRIPTION PROCESSING~~ **CENTRAL FILL** PHARMACIES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(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 community health~~ **department of licensing and regulatory affairs** by sections 16145**,** ~~and 17701~~**17753, and 17767** of **the public health code,** 1978 PA 368, MCL 333.16145**,** ~~and 333.17701~~ **333.17753,** ~~et seq.~~ and **333.17767, and** Executive Reorganization Order ~~Numbers~~ **Nos.** ~~1996-1~~ **1991-9**, 1996-2, ~~and~~ 2003-1, **and 2011-4,** ~~being~~ MCL ~~330.3101~~ **338.3501**, 445.2001, ~~and~~ 445.2011 **and 445.2030**)

R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056 of the Michigan administrative code are amended, as follows:

PART 1. GENERAL PROVISIONS

R 338.3051 Definitions.

Rule 1. (1) As used in **these rules** ~~parts 1 and 2 of the centralized prescription processing rules, R 338.3051 to R 338.3054~~:

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

(b) ~~(a)~~ "~~Centralized prescription~~ **Central fill pharmacy**~~processing center~~" means a pharmacy ~~operated under the direction of a pharmacist~~ that ~~processes information related to the practice of pharmacy and~~ engages in centralized prescription processing **at the request of an originating pharmacy**.

~~(b)~~**(c)** "Centralized prescription processing" is the term defined in section 17753(3) of the code.

~~(c)~~**(d)** "Code" means **the public health code,** 1978 PA 368, MCL 333.1101 ~~et seq.~~ **to 333.25211.**

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

~~(d)~~**(f)** "Deliver" as used in this part means **the actual, constructive, or attempted transfer of** ~~to~~ a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. A ~~centralized prescription~~ **central fill** ~~processing center~~ **pharmacy** that provides a prescription product to another

pharmacy for subsequent issuance to a patient or a patient's agent has not met the definition of deliver as defined in this subrule.

~~(e)~~**(g)** "Delivering pharmacist" means a pharmacist who is responsible for delivering a prescription directly to a patient or a patient's agent.

~~(f)~~**(h)** "Delivering pharmacy" means the pharmacy that delivers the filled or refilled prescription to the patient or the patient's ~~authorized representative~~**agent**. The delivering pharmacy shall be either the originating pharmacy or the ~~centralized prescription processing center~~ **central fill pharmacy**.

~~(g)~~ **(i)** "Originating pharmacy" means a pharmacy that initially receives a patient's or a prescribing practitioner's request to fill or refill a prescription.

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

R 338.3052 ~~Centralized prescription~~ **Central fill pharmacies** rules; prevail over other pharmacy rules.

Rule 2. **(a)** To the extent that ~~any rule in parts 1 and 2 of the centralized prescription processing~~ **these** rules ~~conflicts~~ **conflict** with other board ~~of pharmacy~~ rules, the provisions in ~~parts 1 and 2 of the centralized prescription processing~~ **these** rules shall prevail.

(b) Central fill pharmacies must follow the record keeping, data entry, claims processing, and product verification requirements in R

R 338.3053 Centralized prescription processing; requirements.

Rule 3. (1) In addition to complying with the requirements of section 17753 of the code, **MCL 333.17753,** a pharmacy **shall meet all of the following requirements before it either performs** ~~may perform~~ centralized prescription processing ~~services~~ or ~~outsource~~ **outsources** ~~these services~~ **centralized prescription processing** to another pharmacy**:**~~. Pharmacies that perform or outsource prescription processing services shall meet all of the following requirements:~~

(a) ~~Be licensed by the Michigan board of pharmacy~~**The pharmacies shall hold a pharmacy license in this state**.

(b) **The pharmacies shall share** ~~Share~~ sufficient patient and drug information to minimize the possibility of an adverse drug event.

(c) **The pharmacies shall** ~~Maintain~~ **maintain** ~~prescription information or an equivalent record, as prescribed in section 17752(1) of the code, and the~~ records required in R 338.3054 ~~of this part~~, for 5 years **from the date of dispensing**. A ~~centralized prescription processing center~~ **central fill pharmacy** and an pharmacy shall ensure that the information is readily retrievable within 48 hours after the ~~board's agent~~ **department** makes a request for the information. If the records are maintained in a digital format, a printed copy shall be made available **to the department or other authorized individual**~~immediately to the board's agent~~ upon request.

(d) The originating pharmacy shall maintain the original prescription for a period of 5 years from the date the prescription was filled. After 2 years, the originating pharmacy may make an electronic duplicate of the original paper prescription, which will become the original prescription. A pharmacy shall present a printed

copy of the electronic duplicate of the prescription to the department or other authorized individual upon request.

(2) A pharmacy engaging in centralized prescription processing shall be responsible for each function of the prescription's processing performed by that pharmacy.

(3) A delivering pharmacist shall be responsible for complying with ~~R 338.490(4)~~ **R 338.589(4)** regarding patient counseling.

(4) The prescription label for a prescription that was filled by a ~~centralized prescription processing center~~ **central fill pharmacy** shall identify each pharmacy that was involved in ~~preparing~~**dispensing** and delivering a prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** may be identified on a prescription label by use of a unique identifier that is recognized by the delivering pharmacist. As used in this subrule, "unique identifier" means a unique combination of letters, numbers, or symbols that allows the delivering pharmacy to identify the specific ~~centralized prescription processing center~~ **central fill pharmacy** involved in the processing of the prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.

(5) A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, provided that the transfer records are maintained. A ~~centralized prescription processing center~~ **central fill pharmacy** and an originating pharmacy shall establish procedures for the disposition of prescription medication that was not delivered to patients. This medication may be returned to stock and may be ~~re-delivered~~ **re-dispensed** without constituting a violation of R ~~338.472(1)~~ **338.503(1)**.

(6) A pharmacy that performs or contracts for centralized prescription **processing** ~~services~~ shall comply with the procedures described in its policies and procedures manual, as provided in section 17753(2) of the code**, MCL 333.17753**.

R 338.3054 Records maintenance; requirements for ~~centralized prescription processing~~ **central fill** pharmacies.

Rule 4. (1) An originating pharmacy shall maintain records that indicate all of the following:

(a) The date the request for centralized prescription processing ~~services~~ was transmitted to a ~~centralized prescription processing center~~ **central fill pharmacy**.

(b) The method of transmittal.

(c) The identification of the pharmacist responsible for the transmission.

(d) The name and address of the ~~centralized prescription processing center~~ **central fill pharmacy** ~~to which~~ **where** the request for centralized prescription processing ~~services~~ was transmitted.

(e) The date the delivering pharmacy received the filled prescription from the ~~centralized prescription processing center~~ **central fill pharmacy**.

(f) The name of the pharmacy employee who accepted the ~~delivery~~ **transfer** of a filled prescription from a ~~centralized prescription processing center~~ **central fill pharmacy**.

(g) The identification of the pharmacist who was responsible for delivering the prescription to the patient or the patient's agent.

(2) A ~~centralized prescription processing center~~ **central fill pharmacy** that receives the transmitted prescription shall maintain records that indicate all of the following, as applicable to its function:

(a) The date the request for centralized prescription processing ~~services~~ was received from the originating pharmacy.

(b) The name and address of the originating pharmacy from which the request for centralized prescription processing ~~services~~ was received.

(c) The date the prescription was processed, verified, or filled.

(d) The identification of any pharmacist who was responsible for processing the prescription and shipping a filled prescription to an originating pharmacy or delivering a filled prescription to a patient or a patient's agent.

(e) The date the filled prescription was shipped to the originating pharmacy or was shipped or delivered to the patient or the patient's agent.

(f) If shipped, the name and address of the patient to whom the filled prescription was shipped.

(g) The method of delivery, such as private, common, or contract carrier, if shipped.

(3) If a prescription was not delivered to a patient and was transferred back to the pharmacy that filled the prescription, that pharmacy shall maintain the transfer records.

PART 2. CONTROLLED SUBSTANCES PRESCRIPTIONS

R 338.3055 Schedule 2, 3, 4, or 5 controlled substances prescriptions; requirements for ~~centralized prescription processing~~ **central fill** pharmacies.

Rule 5. (1) In addition to complying with the requirements of Part 1 of these rules, a pharmacy that performs or contracts for centralized prescription processing ~~services~~ shall comply with this rule when processing a prescription for a schedule 2, 3, 4, or 5 controlled substance.

(2) Prescriptions for controlled substances may be transmitted electronically, including by facsimile, from an originating pharmacy to a ~~centralized prescription processing center~~ **central fill pharmacy**.

(3) An originating pharmacy that transmits prescription information for a controlled substance to a ~~centralized prescription processing center~~ **central fill pharmacy** shall comply with all of the following:

(a) **The originating pharmacy shall ensure** ~~Ensure~~ that the words "CENTRAL FILL" are on the face of the original prescription and record all of the following information:

(i) ~~the~~ **The** name, address, and the ~~federal drug enforcement administration (dea)~~ **Federal Drug Enforcement Administration (DEA)** registration number of the ~~centralized prescription processing center~~ **central fill pharmacy** ~~to which~~ **where** the prescription ~~had been~~ **was** transmitted~~;~~ **.**

(ii) ~~the~~ **The** name of the pharmacist at the originating pharmacy who transmitted the prescription~~;~~ **.**

(iii) ~~and, the~~ **The** date of transmittal.

(b) **The originating pharmacy shall ensure** ~~Ensure~~ that all information that is required to be on a prescription pursuant to the provisions of 21 **CFR**~~C.F.R. §~~**section** 1306.05 and R 338.3161 is transmitted to the ~~centralized prescription processing center~~

central fill pharmacy either on the face of the original prescription or in the electronic transmission of **the** prescription ~~information~~.

(c) **The originating pharmacy shall** ~~Indicate~~ **include all of the following** in the prescription ~~information that is transmitted,~~.

(i) ~~the~~ **The** number of refills already dispensed**.**

(ii) ~~and the~~ **The** number of refills remaining.

(d) **The originating pharmacy shall maintain**~~Maintain~~ the original prescription for a period of 5 years from the date the prescription was filled. **After 2 years, the originating pharmacy may make an electronic duplicate of the original printed prescription, which will become the original prescription. A pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or other authorized individual upon request.**

(4) In addition to complying with the requirements in R ~~338.3053~~**338.3054**(2)(a), (b), (c), (d), (e), (f) and (g), a ~~centralized prescription processing center~~**central fill pharmacy** that receives the transmitted prescription shall comply with both of the following:

(a) **The central fill pharmacy shall maintain**~~Maintain~~ records for 5 years **from the date of transmittal**.

(b) Keep a copy of the prescription if it was sent via facsimile or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and ~~dea~~ **DEA** registration number of the originating pharmacy that transmitted the prescription.

(c) Keep a record of the date the filled prescription was dispensed and the method of dispensed.

R 338.3056 Reporting to the electronic system for monitoring controlled substances.

Rule 6. As used in this part, the pharmacy that uses its stock to fill a prescription for a controlled substance shall be the pharmacy responsible to report to the department or the department's contractor the information required in R 338.3162b for each **controlled substance** prescription ~~of a controlled substance~~.

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) Δ1 cis or trans tetrahydrocannabinol, and their optical isomers.
(ii) Δ6 cis or trans tetrahydrocannabinol, and their optical isomers.
(iii) Δ3,4, 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) Ask the Board if the one day requirement, consistent with the DEA, is preferred.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 pf the prescriber 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 - GENERAL RULES

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 16141, 16145, 16148, 16174, 16175, 16178, 16182, 16186, 16204, 16205, 16215, 16287, 17707, 17721, 17722, 17731, 17737, 17739, 17742a, 17742b, 17746, 17748, 17748a, 17748b, 17748e, 17751, 17753, 17754a, 17757, 17760, 17767, and 17775 of the public health code, 1978 PA 368, MCL 333.16141, 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.16204, 333.16205, 333.16215, 333.16287, 333.17707, 333.17721, 333.17722, 333.17731, 333.17737, 333.17739, 333.17742a, 333.17742b, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17748e, 333.17751, 333.17753, 333.17754a, 333.17757, 333.17760, 333.17767, and 333.17775 and Executive Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.486, etc of the Michigan Administrative Code is amended as follows:

ADMINISTRATIVE HEARINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.
(5) Upon recommendation of an interdisciplinary practitioners' committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.
(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient, or a unique identifier, must be labeled on the medication container. The container may be the individual patient's assigned medication drawer. The directions for use must be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use must be on the container. The provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.
(7) A pharmacist shall supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, MCL 333.7101 to 333.7125, dispensed to patients. However, medications in single-unit packages and intravenous solutions which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for dispensing.
(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board, upon request.

PHARMACY SERVICES IN MEDICAL INSTITUTIONS

PART 1. GENERAL PROVISIONS

R 338.501 Definitions.
Rule 1. (1) As used in these rules:
(a) "Approved education program" means a school of pharmacy that is accredited by or has candidate status by the Accreditation Council for Pharmacy Education (ACPE).
(b) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.
(c) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.
(d) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under any of the following circumstances:
(i) Upon the receipt of a prescription for a specific patient.

(ii) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.
(iii) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.
(iv) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.
(e) "Compounding" does not include any of the following:
(i) Except as provided in section 17748c of the code, MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product.
(ii) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.
(iii) The compounding of allergenic extracts or biologic products.
(iv) Flavoring agents added to conventionally manufactured and commercially available liquid medications. Flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume.
(f) "Department" means the department of licensing and regulatory affairs.
(g) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by an individual with the intent to sign the record. An electronic signature is a unique identifier protected by appropriate security measures that is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.
(h) "Error prevention technology" means machinery and equipment used in a pharmacy setting to reduce dispensing medication errors including, but not limited to, barcode verification and radio frequency identification.
(i) "Manual signature" means a signature that is handwritten or computer-generated if a prescription is electronically transmitted as defined in section 17703(8) of the code, MCL 333.17703.
(j) "Practical experience" means professional and clinical instruction in, but not limited to, all of the following areas:
(i) Pharmacy administration and management.
(ii) Drug distribution, use, and control.
(iii) Legal requirements.
(iv) Providing health information services and advising patients.
(v) Pharmacist's ethical and professional responsibilities.
(vi) Drug and product information.
(vii) Evaluating drug therapies and preventing or correcting drug-related issues.
(k) "Virtual manufacturer" means a person who engages in the manufacture of prescription drugs or devices and meets all of the following:
(i) Owns either of the following:
(A) The new prescription drug application or abbreviated new prescription drug application number.
(B) The unique device identification number, as available, for a prescription device.
(ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices.
(iii) Is not involved in the physical manufacture of the drugs or devices.

(iv) At no time takes physical possession of or stores the drugs or devices.
(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.
(l) "Written" includes both paper and electronic forms.
(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning when used in these rules.

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.
Rule 3. (1) Prescription drugs or devices that have been dispensed and have left the control of the pharmacist must not be returned or exchanged for resale.
(2) This rule does not apply to any of the following:
(a) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail, as provided in section 17766d of the code, MCL 333.17766d.
(b) A pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided in section 17775 of the code, MCL 333.17775.
(c) A pharmacy or health facility that participates in the cancer drug repository program, as provided in section 17780 of the code, MCL 333.17780.
(d) Drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. Subject to R 338.486(7), in no instance may returned drugs be reused or returned to active stock.

R 338.505 Inspection of applicants and licensees.
Rule 5. (1) The board, board inspector, board agent, or an entity approved pursuant to R 338.532, may enter at reasonable times, any building, place, or facility that is owned or controlled by any applicant for, or holder of, a license to inspect to enable the board to determine if the applicant possesses the qualifications and competence for the license sought or to determine whether a license holder is and has been complying with the code and rules. The inspection must concern only matters relevant to the applicant's or license holder's practice of pharmacy, manufacturing, and wholesale distributing of drugs and devices saleable by prescription only.
(2) Inspections in subrule (1) of this rule must not extend to any of the following information, however, the following information is subject to a disciplinary investigation:
(a) Financial data.
(b) Sales data other than shipment data.
(c) Pricing data.
(d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.
(e) Research data.
(3) An applicant or license holder shall permit and cooperate with the inspection.

PART 2. PHARMACIST LICENSES

R 338.511 Training standards for identifying victims of human trafficking; requirements.
Rule 11. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual seeking licensure or who is licensed shall complete training in identifying victims of human trafficking that meets the following standards:
(a) Training content must cover all of the following:
(i) Understanding the types and venues of human trafficking in the United States.
(ii) Identifying victims of human trafficking in health care settings.
(iii) Identifying the warning signs of human trafficking in health care settings for adults and minors.
(iv) Resources for reporting the suspected victims of human trafficking.
(b) Acceptable providers or methods of training include any of the following:
(i) Training offered by a nationally recognized or state-recognized, health-related organization.
(ii) Training offered by, or in conjunction, with a state or federal agency.
(iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.
(iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer reviewed journal, health care journal, or professional or scientific journal.
(c) Acceptable modalities of training may include any of the following:
(i) Teleconference or webinar.
(ii) Online presentation.
(iii) Live presentation.
(iv) Printed or electronic media.
(2) The department may select and audit a sample of individuals and request documentation of proof of completion of training. If audited by the department, an individual shall provide an acceptable proof of completion of training, including either of the following:
(a) Proof of completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.
(b) A self-certification statement by an individual. The certification statement must include the individual's name and either of the following:
(i) For training completed pursuant to subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.
(ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer review journal, health care journal or professional or scientific journal, and date, volume, and issue of publication as applicable.
(3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning January 1, 2020 and for initial licenses issued after November 13, 2022.

R 338.513 Educational limited license; application and renewal; practices.
Rule 13. (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the

requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and MCL 333.17737, the applicant shall establish either of the following:
(a) That the applicant is actively enrolled in, or is within 180 days of completing, an approved educational program.
(b) That the applicant has received a Foreign Pharmacy Graduate Examination Committee (FPGEC) certification from the National Association of Boards of Pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, Illinois, 60056, https://nabp.pharmacy/programs/fpgec/.)
(2) The educational limited license must be renewed annually as follows:
(a) At the time of renewal, the applicant shall submit verification to the department that he or she is actively enrolled in, or is within 180 days of completing, an approved educational program. The educational limited license is valid for 1 year.
(b) If an applicant is a graduate of a non-accredited college or school of pharmacy at the time of renewal, the applicant shall submit verification to the department from his or her preceptor that the applicant is currently in an internship program under the preceptor's supervision. The educational limited license is valid for 1 year and may be renewed 1 time.
(3) An educational limited licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist.
(4) An educational limited licensee shall verify that his or her pharmacy preceptor holds a valid preceptor license prior to engaging in the practice of pharmacy if the internship hours will be submitted to the department for credit.
(5) An educational limited licensee shall notify the board within 30 days if he or she is no longer actively enrolled in an approved educational program.
(6) An applicant for an educational limited license shall meet the requirements of R 338.511.

R 338.515 Internship requirements.
Rule 15. (1) An internship must be a minimum of 1,600 hours, subject to all of the following:
(a) Not more than 40 hours per week may be earned.
(b) An unconventional internship requires prior board approval and is limited to a maximum of 400 hours, with a maximum of 16 hours earned per week, and not more than 40 hours earned per week when the intern's pharmacy school is not in session.
"Unconventional internship" means an educational program of professional and practical experience involving the pharmacy or related pharmaceutical experiences which, through on-the-job training, provides knowledge useful to the practice of the profession of pharmacy. **An individual participating in an unconventional internship shall annually submit to the department an affidavit from the internship supervisor that includes the type of activities performed and the number of internship hours completed.**
(c) **For all internships except unconventional internships,** ~~The~~ **the** licensed pharmacy preceptor, an approved education program, or other person previously approved by the board shall verify ~~the~~ **internship** hours.
(2) The internship must provide professional and practical experience.

(3) If an internship is not completed through an approved educational program or under the personal charge of a preceptor licensed in this state, the individual shall petition the board for approval of hours. Talk about the application of this section?
(4) An individual shall obtain an educational limited license pursuant to R 338.513 before starting an internship that includes the practice of pharmacy in this state.

R 338.517 Preceptor license and responsibilities.
Rule 17. (1) An applicant for licensure as a pharmacist preceptor shall submit to the department a completed application on a form provided by the department.
(2) The applicant shall satisfy both of the following:
(a) Have an unrestricted pharmacist license from this state that is in good standing for the past year.
(b) Have been engaged in the practice of pharmacy in this state for at least 1 year.
(3) A preceptor shall do all of the following:
(a) Ensure that the pharmacist on duty is supervising not more than 2 pharmacist interns at the same time. The approved preceptor is responsible for the overall internship program at the pharmacy.
(b) Determine the degree of the intern's professional skill on the topics listed in R 338.501(1)(j) and develop a training program whereby the intern can improve his or her skill in these areas.
(c) Ensure sufficient time to instruct the intern on the topics in R 338.501(1)(j) and review and discuss the intern's progress on the topics in R 338.501(1)(j).
(d) Annually submit to the department training affidavits that include the number of internship hours completed by the intern in the practice of pharmacy.

R 338.519 Examinations adoption; passing scores; reexamination.
Rule 19. (1) The board adopts the North American pharmacist licensure examination (NAPLEX) developed and administered by the NABP.
~~(2) The board adopts the Michigan multistate pharmacy jurisprudence examination (MPJE) that is developed and administered by NABP.~~
~~(3)~~**(2)** The passing score for the NAPLEX ~~or the MPJE~~ accepted for licensure will be the passing score established by the NABP.
~~(4)~~**(3)** An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is longer. An applicant who has not achieved a passing score on the NAPLEX may not take the NAPLEX more than 3 times in a 12-month period.
~~(5)~~**(4)** ~~An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is longer.~~
~~(6)~~**(5)** If an applicant for licensure fails to pass ~~either of these~~ **the NAPLEX** ~~examinations,~~ within 3 attempts, the applicant shall request preapproval from the department, after consultation with a board member, if necessary, of a live or interactive examination preparation course, or instruction with an instructor with expertise on the subject matter, for the examination that he or she failed. After participating in the course or instruction the applicant shall provide the department with proof that he or she completed the course or instruction.

~~(7)~~**(6)** An applicant may not sit for the NAPLEX specified in subrule (4) of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i) and provides proof of completion to the department.
~~(8) An applicant may not sit for the MPJE specified in subrule (5) of this rule more than 5 times, unless he or she successfully repeats an approved pharmacy law course in an educational program, as specified in R 338.521(2)(a)(i) and provides proof of completion to the department.~~

R 338.521 Pharmacist licensure by examination.
Rule 21. (1) An applicant for licensure as a pharmacist by examination shall submit to the department a completed application on a form provided by the department with the requisite fee.
(2) In addition to meeting the requirements of section 16174 of the code, MCL 333.16174, an applicant for licensure shall satisfy all of the following requirements:
(a) Have earned either of the following:
(i) A professional degree from a school of pharmacy accredited by the ACPE.
(ii) A FPGEC certification from the NABP. An applicant who has an FPGEC certification from NABP has met the English proficiency requirement as the applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.
(b) Passed ~~the MPJE and~~ the NAPLEX.
(c) Completed an internship as set forth in R 338.515.
(d) Completed a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.
(e) Completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.
(f) Submitted proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004. An applicant who has an FPGEC certification from NABP has met the English proficiency requirement as the applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.
(3) An applicant 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 338.523 Pharmacist license by endorsement; requirements.
Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.
(2) An applicant shall satisfy all of the following requirements:
(a) Establish 1 of the following:

(i) He or she holds a license in good standing as a pharmacist in another state and submits the NABP licensure transfer report to the department.
(ii) He or she holds a pharmacy license in Canada that is in good standing and meets all of the following:
(A) He or she has passed the NAPLEX or both part I and part II of the Pharmacy Examining Board of Canada (PEBC) Pharmacists Qualifying Examination.
(B) He or she completed educational requirements for a pharmacist license from a school of pharmacy accredited by the ACPE or accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).
(C) If he or she held a pharmacist license for less than 1 year in Canada, he or she had acquired a minimum of 1,600 hours of pharmacy practice either through an approved internship or hours engaged in the practice as a pharmacist.
~~(b) Pass the MPJE as required under R 338.519.~~
~~(c)~~**(b)** 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:
(i) Disclose each license, registration, or certification on the application form.
(ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which include verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.
~~(d)~~**(c)** He or she meets section 16174 of the code, MCL 333.16174, and submits his or her fingerprints to the department of state police to have a criminal background check conducted by the state police and the federal bureau of investigation.
~~(e)~~**(d)** He or she completes a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.
~~(f)~~**(e)** He or she completes a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.
~~(g)~~**(f)** He or she submits proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004.
(3) An applicant who has an FPGEC certification from NABP has met the English proficiency requirement. The applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

R 338.525 Relicensure of a pharmacist license; requirements.
Rule 25. (1) An applicant for relicensure whose pharmacist license has lapsed in this state, under sections 16201(3) or (4) and 17733 of the code, MCL 333.16201and MCL 333.17733, as applicable, may be relicensed by complying with the following requirements as noted by (x):

For a pharmacist who has let his or her license lapse in this state and who is not currently licensed in another state or a province of Canada:	License lapsed 0-3 years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department,	X	X	X

with the requisite fee.			
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Continuing education: submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	X	X	X
~~(e) Pass MPJE: retake and pass the MPJE as provided in R 338.519.~~		X	X
~~(f)~~**(e)** Submit proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, a 1-time training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
~~(g)~~**(f)** Practical experience: complete 200 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of of being granted a limited license.		X	
~~(h)~~**(g)** Practical experience: complete 400 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of of being granted a limited license.			X
~~(i)~~**(h)** Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R			X

338.519.			
~~(i)~~**(i)** 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: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which includes 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.	X	X	X

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

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

(4) For a pharmacist who has let his or her pharmacist license lapse in this state, but who holds a current and valid pharmacist license in good standing in another state or a Canadian province:	License lapsed 0-3 Years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Continuing education: submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted	X	X	X

with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.			
(e) Submit proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, a 1-time training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
~~(f) Examination: retake and pass the MPJE as provided in R 338.519.~~		X	X
(g) 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: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which includes 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.	X	X	X

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

PART 3. PHARMACY LICENSES

R 338.531 Pharmacy license; remote pharmacy license; applications; requirements.
Rule 31. (1) An applicant for a pharmacy license or a remote pharmacy license shall submit to the department a completed application on a form provided by the department together with the requisite fee.
(2) An applicant shall submit all of the following information:
(a) Certified copies of articles of incorporation or partnership certificates and certified copies of assumed name certificates, if applicable.

(b) Submission of fingerprints for the purpose of a criminal history background check required under section 17748(6) of the code, MCL 333.17748.
(c) A federal employer identification number (FEIN) certificate.
(d) The name and license number of the pharmacist in this state designated as the pharmacist in charge (PIC) pursuant to section 17748(2) of the code, MCL 333.17748, who must have a valid and unrestricted license.
(e) The identity and address of each partner, officer, or owner, as applicable.
(f) A completed self-inspection form.
(g) If the applicant intends to provide compounding services, proof of application with an entity that satisfies the requirements of R 338.532.
(h) An inspection report that satisfies the requirements of R 338.534.
(i) If the applicant is an in-state pharmacy that intends to compound pharmaceutical products, the applicant shall submit to an inspection from an approved accrediting organization under R 338.532.
(j) If the applicant is a governmental entity, an individual must be designated as the licensee. The licensee and the pharmacist on duty shall be responsible for complying with all federal and state laws regulating the practice of pharmacy and the dispensing of prescription drugs.
(k) If the applicant is applying for a remote pharmacy license, the applicant shall submit the following:
(i) Ownership documents to demonstrate to the satisfaction of the department that the parent pharmacy and the proposed remote pharmacy share common ownership.
(ii) Copies of the policies and procedure manual required in section 17742b of the code, MCL 333.17742b.
(iii) A map showing all of the existing pharmacies within 10 miles of the proposed remote pharmacy if the remote pharmacy will not be located at a hospital or mental health facility.
(l) If the applicant is or has ever been licensed, registered, or certified as a pharmacy by any other state, the United States military, the federal government, or another country, the applicant shall do both of the following:
(i) Disclose each license, registration, or certification on the application form.
(ii) Submit verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.
(3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared or dispensed, each address location must obtain a separate license.

R 338.531a Remote pharmacy waiver from mileage requirement.
Rule 31a. (1) An applicant seeking a remote pharmacy license may apply to the board for a waiver from the prohibition of locating a remote pharmacy within 10 miles of another pharmacy in section 17742a(2)(c) of the code, MCL 333.17742a, by submitting a completed application to the department, on a form provided by the department.
(2) The applicant shall submit the following with the application:
(a) A map showing the location of any existing pharmacies within 10 miles of the proposed remote pharmacy if the remote pharmacy will not be located at a hospital or mental health facility.

(b) A list and explanation of the services or availability of services that will be offered at the remote pharmacy or otherwise not readily available to patients that are different from the services offered at a pharmacy located within 10 miles of the proposed remote pharmacy.
(c) A statement of facts to support the statement of 1 or more of the following:
(i) The proposed remote pharmacy is located in an area where there is limited access to pharmacy services.
(ii) The proposed remote pharmacy will offer a service or the availability of a service that is unique from other pharmacies in the 10-mile radius from the remote pharmacy and the service will satisfy an unmet need of the surrounding community.
(iii) There exists a limitation on travel that justifies waiving the requirement.
(iv) There are other compelling circumstances that justify waiving the requirement.
(3) If the waiver is denied, the application is considered closed unless within 30 days of receipt of the denial, the applicant notifies the department that it is requesting a hearing on the matter.

R 338.532 Compounding accrediting organizations; board approval; inspection entities.
Rule 32. (1) The board shall approve, under section 17748a of the code, MCL 333.17748a, accrediting organizations or inspection entities for pharmacies that compound-pharmaceuticals according to standards adopted by reference in R 338.533.
(2) The department shall post on its website, the list of organizations approved under subrule (1) of this rule.
(3) An organization may petition the board for approval under subrule (1) of this rule. The petition must include, but not be limited to, all of the following:
(a) Requirements for accreditation or compliance.
(b) Requirements for inspectors.
(c) Training provided to inspectors.
(d) Copy of the most current inspection form.
(e) The length of accreditation.
(f) Agreement and plan to share results of inspections with the department.
(4) If the board approves the petition, the approval is valid for 3 years from the date of approval. The organization may submit a petition that complies with subrule (3) of this rule to seek continuing approval.
(5) The board may rescind approval of an organization upon just cause. The rescission will not immediately affect the compliance of a pharmacy using the accreditation. Within 12 months of the rescission date or by the next licensure renewal date, whichever is later, the accreditation is void, and a pharmacy shall obtain accreditation or an inspection from an organization that satisfies subrule (1) of this rule.

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.
Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland, 20852-1790. This includes, but is not limited to, USP Chapters 795 and 797.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at http://www.usp.org/compounding, or at a cost of 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.
(3) A pharmacy that provides compounding services shall comply with all current standards adopted in subrule (1) of this rule.
(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state must be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state.
(5) A licensed outsourcing facility shall submit to the board a copy of the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form.
(6) An outsourcing facility shall do all of the following:
(a) Compound drugs by or under the supervision of a licensed pharmacist.
(b) Compound drugs pursuant to current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208 (2021).
(c) Ensure that a pharmacist who conducts or oversees compounding at an outsourcing facility is proficient in the practice of compounding and has acquired the education, training, and experience to maintain that proficiency by doing any of the following:
(i) Participating in seminars.
(ii) Studying appropriate literature.
(iii) Consulting with colleagues.
(iv) Being certified by a compounding certification program approved by the board.
(d) Label compounded drugs with all of the following and label compounded drugs that are patient specific with all of the following and consistent with the requirements in R 338.582:
(i) Required drug and ingredient information.
(ii) Facility identification.
(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."
(e) Ensure that bulk drug substances used for compounding meet specified FDA criteria.
(7) An outsourcing facility may compound drugs that appear on an FDA shortage list, if the bulk drug substances used to compound the drugs comply with the criteria specified in this rule.

R 338.534 Inspections.
Rule 34. (1) A pharmacy located outside of this state that applies for licensure in this state as a pharmacy that will not ship compounded sterile pharmaceutical products into this state shall submit to the department a copy of its most recent pharmacy inspection that was performed within the last 2 years from the date of application.
(2) An applicant for a new pharmacy located in this state shall have an inspection conducted by the department or its designee prior to licensure.
(3) Unless accredited by a national accrediting organization, recognized by the board, an applicant for licensure or renewal of an in-state or out-of-state pharmacy that will provide

sterile compounded pharmaceuticals in this state shall have an inspection and submit the inspection report to the department, completed no more than 18 months before the date of application, that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533. The inspection must be conducted by 1 of the following:
(a) The department.
(b) The NABP-Verified Pharmacy Program (NABP-VPP).
(c) An accrediting organization according to R 338.532.
(d) A state licensing agency of the state in which the applicant is a resident and in accordance with the NABP's multistate pharmacy inspection blueprint program.

R 338.535 Discontinuing, starting, or resuming sterile compounding services; requirements to resume sterile compounding services.
Rule 35. (1) A sterile compounding pharmacy or outsourcing facility that ceases to provide sterile compounding services in this state shall notify the department within 30 days of ceasing to provide sterile compounding services.
(2) A pharmacy shall apply for approval to start or resume sterile compounding services by submitting to the department an application on a form provided by the department together with the requisite fee.
(3) A pharmacy shall not start or resume sterile compounding services in this state until the pharmacy submits to the department an inspection report as required in R 338.534(3), is approved by the department, and is accredited or an organization satisfying the requirements of R 338.532(1) verifies that the pharmacy is USP compliant.
(4) An outsourcing facility shall not start or resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant with the requirements of R 338.533(4) to (7).

R 338.536 Housing of a pharmacy.
Rule 36. (1) All professional and technical equipment and supplies and prescription drugs must be housed in a suitable, well-lighted, and well-ventilated room or department with clean and sanitary surroundings.
(2) All pharmacies shall have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist who is on duty at any 1 time, the free working space must be increased by not less than 4 square feet. The prescription counter must be kept orderly and clean. The space behind the prescription counter must be sufficient to allow free movement within the area and must be free of obstacles.
(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling. All partitions must be of substantial construction and must be securely lockable so that drugs and devices that can be sold only by a pharmacist will be unobtainable during the absence of the pharmacist. Only the area of the premises owned, leased, used, or controlled by the licensee may be identified by the terms "drugstore," "apothecary," or "pharmacy," or by use of a similar term or combination of terms as listed in section 17711(2) of the code, MCL 333.17711. A pharmacy department must be locked when the pharmacist is not on the premises.

R 338.537 Professional and technical equipment and supplies.
Rule 37. A pharmacy must be equipped with both of the following:
(a) The necessary facilities, apparatus, utensils, and equipment to permit the pharmacy to provide prompt and efficient services.
(b) Current print, electronic, or internet accessible editions of the Michigan pharmacy laws and rules, and at least 2 current pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition.

R 338.538 Closing pharmacy.
Rule 38. (1) A pharmacy that is ceasing operations shall return to the department the pharmacy license and the controlled substance license, if applicable, and provide the department with written notification of all of the following at least 15 days prior to closing:
(a) The effective date of closing.
(b) How controlled substances will be disposed.
(c) How non-controlled substances will be disposed.
(d) The location where records and prescription files will be stored.
(2) A pharmacy shall comply with all applicable federal requirements for discontinuing operation as a pharmacy that dispenses controlled substances.
(3) Records must be maintained for the same amount of time that is required if the pharmacy remained open.

R 338.539 Relicensure and renewal.
Rule 39. (1) An applicant with an expired license may apply for relicensure of a pharmacy license by submitting to the department a completed application on a form provided by the department, satisfying all the requirements for licensure in part 3 of these rules, R 338.531 to R 338.539, and paying the requisite fee.
(2) A pharmacy that renews its license during the license renewal period submit to the department a completed application, on a form provided by the department, together with the requisite fee.

PART 4. MANUFACTURER LICENSE

R 338.551 Manufacturer license; application.
Rule 51. (1) An applicant for a manufacturer license shall submit to the department a completed application on a form provided by the department with the requisite fee.
(2) An applicant shall provide all of the following information:
(a) A criminal history background check required pursuant to section 17748(6) of the code, MCL 333.17748.
(b) A FEIN certificate.
(c) Certified copies of articles of incorporation or certificates of partnership and assumed name certificates, if applicable.
(d) The identity and address of each partner, officer, or owner, as applicable.
(e) A completed compliance checklist for manufacturers.

(f) A list or a catalog of all drug products or devices to be manufactured by the facility.
(g) Unless exempt under section 17748(2) of the code, MCL 333.17748, the name and license number of the pharmacist designated as the PIC or the name of the facility manager. For an individual who is designated as a facility manager, the applicant shall provide proof, in the form of an affidavit, that the facility manager has achieved the following:
(i) A high school equivalency education, or higher, defined as 1 of the following:
(A) A high school diploma.
(B) A general education development certificate (GED).
(C) A parent-issued diploma for home schooled individuals.
(D) Completion of post-secondary education, including either an associate's degree, a bachelor's degree, or a master's degree.
(ii) Completion of a training program that includes, but is not limited to, all of the following subjects:
(A) Knowledge and understanding of laws in this state and federal laws relating to the distribution of drugs and devices.
(B) Knowledge and understanding of laws in this state and federal laws relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.
(E) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.
(iii) Experience equal to either of the following:
(A) A minimum of 1 year of work experience related to the distribution or dispensing of prescription drugs or devices where the responsibilities included, but were not limited to, recordkeeping.
(B) Previous or current employment as a designated representative of a manufacturer.
(iv) Employment with the applicant.
(h) A copy of the FDA certification for the site to be licensed, if an applicant is a manufacturer of biologicals.
(i) An inspection from the manufacturer's resident state board of pharmacy or verified-accredited wholesale distributors (VAWD) accreditation dated not more than 2 years prior to the application.
(j) An applicant that is or has ever been licensed, registered, or certified as a manufacturer by any other state, the United States military, the federal government, or another country, shall do both of the following:
(i) Disclose each license, registration, or certification on the application form.
(ii) Submit verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.
(3) A separate license is required for each location where prescription drugs or devices are manufactured.
(4) A manufacturer who changes its facility manager shall submit all of the information required in subrule (2)(i) of this rule to the department within 30 days of the change.

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

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

R 338.555 Federal regulation on good manufacturing practice for finished pharmaceuticals; adoption by reference; compliance.
Rule 55. (1) The board approves and adopts by reference the current good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (2021).
(2) A manufacturer shall comply with the standards adopted in subrule (1) of this rule.
(3) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211, or at 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.

R 338.557 Closure of a manufacturer.
Rule 57. (1) A manufacturer that is ceasing operations shall return the manufacturer license and the controlled substance license, if applicable, to the department, and provide the department with written notification of all of the following at least 15 days prior to closing:
(a) The effective date of closing.
(b) How controlled substances will be disposed.
(c) How non-controlled substances will be disposed.
(d) The location where records and prescription files will be stored.
(2) A manufacturer shall comply with all applicable federal requirements for discontinuing a controlled substance business.
(3) Records must be maintained for the same amount of time that is required if the manufacturer remains open.

R 338.559 Relicensure and renewal.
Rule 59. (1) An applicant with an expired license may apply for relicensure of a manufacturer license by submitting to the department a completed application on a form provided by the department, satisfying all the requirements for licensure in part 3 of these rules, R 338.531 to R 338.539, and paying the requisite fee.
(2) A manufacturer that renews its license during the license renewal period shall submit to the department a completed application on a form provided by the department together with the requisite fee.

PART 5. WHOLESALE DISTRIBUTOR AND WHOLESALE DISTRIBUTOR-BROKER LICENSE

R 338.561 Pharmacy as wholesale distributor; licensure.

Rule 61. A pharmacy shall obtain a license as a wholesale distributor under this part if the total number of dosage units of all prescription drugs distributed by the pharmacy to a person during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the same 12-month period. The calculation of this 5% threshold must not include a distribution of a prescription drug that is exempt from the definition of wholesale distribution under 21 USC 353(e)(4).

R 338.563 Wholesale distributor, wholesale distributor-broker; application for licensure; requirements.

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

(2) An applicant shall comply with all of the following:

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

(b) Disclose on the application form 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.

(c) 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.

(d) Provide certified copies of articles of incorporation or certificates of partnership and assumed names if applicable.

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

(f) Provide a completed compliance checklist.

(g) Provide a FEIN certificate.

(h) Provide a copy of the FDA certification, if a certification is required by the FDA, for the site to be licensed, if the applicant is distributing biologicals.

(i) Unless exempt under section 17748(2) of the code, MCL 333.17748, provide the name and the license number of the pharmacist designated as the PIC or the name of the facility manager. For individuals designated as a facility manager, the applicant shall provide proof, in the form of an affidavit, that the facility manager has achieved the following:

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

(A) A high school diploma.

(B) A GED.

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.
(E) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.
(iii) Experience equal to either of the following:
(A) A minimum of 1 year of work experience related to the distribution or dispensing of prescription drugs or devices where the responsibilities included, but were not limited to, recordkeeping.
(B) Previous or current employment as a designated representative of a wholesale distributor certified by the VAWD of NABP or of a wholesale distributor-broker.
(iv) Current employment with the applicant.
(j) Provide a list or catalog of all drug products and devices to be distributed, if a wholesale distributor.
(k) Submit an affidavit, at the time of the application for initial licensure, that the applicant facilitates deliveries or trades for at least 50 qualified pharmacies and that each pharmacy holds a license in good standing as a pharmacy from the state in which it is located at the time of application, if a wholesale distributor-broker.
(3) A wholesale distributor or wholesale distributor-broker that changes its facility manager shall submit all of the information required in subrule (2)(i) of this rule to the department within 30 days of the change.

R 338.565 Persons to whom prescription drugs and devices may be sold.
Rule 65 A wholesale distributor of prescription drugs or devices may supply, distribute, sell, barter, or otherwise transfer prescription drugs or devices only to persons who are licensed by the board to distribute, prescribe, or dispense prescriptions drugs or devices in or outside this state.

R 338.567 Wholesale distributor practices; control of prescription drugs or devices; inspections.
Rule 67. (1) A wholesale distributor that does not physically touch prescription drugs or devices shall file an affidavit with the department signed by the PIC or facility manager attesting to this fact.
(2) A wholesale distributor that previously filed an affidavit under subrule (1) of this rule shall not obtain custody and control of drugs or devices until both of the following have occurred:
(a) The licensee provides written notification to the department of physical custody.
(b) The department conducts an inspection of the premises.

R 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.
Rule 69. (1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt, if applicable, and the distribution or other disposition of prescription drugs or devices. These records must include all of the following information:

(a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped.
(b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of.
(c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.
(2) A wholesale distributor shall establish and maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
(3) A wholesale distributor shall have written policies and procedures that include all of the following:
(a) A procedure whereby the oldest stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.
(b) A procedure for handling recalls and withdrawals of the prescription drugs or devices. The procedure must deal with recalls and withdrawals due to any of the following:
(i) Any action initiated at the request of the FDA; other federal, state, or local law enforcement agency; or other governmental agency.
(ii) Any voluntary action by the manufacturer to remove defective or potentially defective prescription drugs or devices from the market.
(iii) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.
(c) A procedure to ensure that a wholesale distributor prepares for, protects against, and handles, any crises that affects security or operation of any facility in the event of employee strike, flood, fire, or other natural disaster, or other local, state, or national emergency.
(d) A procedure to ensure that any outdated prescription drugs or devices will be segregated from other prescription drugs or devices and either returned to the manufacturer or destroyed. This procedure must include a provision for the written documentation of the disposition of outdated prescription drugs or devices that must be maintained for 2 years after the disposition of the outdated prescription drugs or devices.
(e) Procedures for identifying, recording, and reporting losses or thefts of prescription drugs or devices and for correcting errors and inaccuracies in inventory.
(4) A wholesale distributor-broker shall establish and maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug delivery and trade, including a description of their duties and a summary of their qualifications.
(5) A wholesale distributor-broker shall maintain for at least 7 years the transaction history, transaction statements, and transaction information required by section 17748e of the code, MCL 333.17748e.
(6) The records described in subrules (1) to (5), and (8) of this rule and section of 17748e of the code, MCL 333.17748e, must be made available for inspection and photocopying by the department, board, authorized federal, state, or local law enforcement agency officials. The records that are kept on-site or that are immediately retrievable by computer or other electronic means must be readily available for an authorized inspection

during the retention period described in subrules (5) and (7) of this rule. Records that are kept at a central location apart from the site must be made available for inspection within 2 working days of a request.
(7) A wholesale distributor shall retain the records described in this rule for a minimum of 2 years after the disposition of the prescription drugs or devices.
(8) A purchasing pharmacy using a wholesale distributor-broker to facilitate a transaction from a pharmacy that is not licensed in Michigan shall request the transaction history, transaction statement or transaction information for the drugs supplied.

R 338.571 Facility requirements.
Rule 71. (1) A wholesale distributor that has physical custody or control of the prescription drugs or devices shall satisfy all of the following facility requirements:
(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.
(b) Have storage areas that are designed to provide for adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.
(c) Have a quarantine area for the storage of prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, adulterated, or that are in immediate or sealed secondary containers that have been opened.
(d) Be maintained in a clean and orderly condition.
(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
(f) Be secure from unauthorized entry by complying with all of the following:
(i) Access from outside the premises must be kept to a minimum and be well-controlled. The outside perimeter of the premises must be well-lighted. Entry into areas where prescription drugs or devices are held must be limited to authorized personnel.
(ii) Be equipped with an alarm system to detect entry after hours.
(iii) Be equipped with a security system that will provide protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(2) All prescription drugs or devices must be stored at temperatures and under appropriate conditions pursuant to the label requirements or pursuant to the requirements set forth in the current edition of the USP compendium. If storage requirements are not established for a prescription drug, the drug may be held at a controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment devices, or logs must be utilized to document the proper storage of prescription drugs or devices.

R 338.573 Examination of materials; returned, damaged and outdated prescription drugs or devices.
Rule 73. (1) A wholesale distributor shall comply with both of the following provisions that pertain to the examination of materials:
(a) Each outside shipping container must be visually examined upon receipt for the identity of the prescription drug or devices and to prevent the acceptance of contaminated prescription drugs or devices or prescription drugs or devices otherwise unfit for

distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(b) Each outgoing shipment must be visually inspected for identity of the prescription drug products and to ensure that prescription drugs or devices that have been damaged in storage or held under conditions that are inconsistent with USP compendium standards are not delivered.
(2) All of the following provisions apply to returned, damaged, and outdated prescription drugs or devices:
(a) Prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, must be quarantined and physically separated from other prescription drugs or devices until they are destroyed or returned to the supplier.
(b) Any immediate or sealed outer or sealed secondary containers of any prescription drugs or devices that have been opened or used must be identified as such and the drugs or devices must be quarantined and physically separated from other prescription drugs or devices until they are either destroyed or returned to the supplier.
(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
(3) The recordkeeping requirements of R 338.569 must be followed.

R 338.575 Closing a wholesale distributor or wholesale distributor-broker.
Rule 75. (1) A wholesale distributor that is ceasing operations shall return the wholesale distributor license and controlled substance license, if applicable, to the department, and shall provide the department with written notification of all of the following at least 15 days prior to closing:
(a) The effective date of closing.
(b) How controlled substances will be disposed.
(c) How noncontrolled substances will be disposed.
(d) The location where records and prescription files will be stored.
(2) A wholesale distributor shall comply with all applicable federal requirements for discontinuing a business that handles a controlled substance.
(3) A wholesale distributor-broker that is ceasing operations shall return the wholesale distributor-broker license and provide the department with written notification of the location where records will be stored at least 15 days prior to closing.
(4) Records must be maintained for the same amount of time that is required if the wholesale distributor or wholesale distributor-broker remained open.

R 338.577 Relicensure and renewal of wholesale distributor and wholesale distributor-broker.

Rule 77. (1) An applicant with an expired license may apply for relicensure of a license by submitting to the department a completed application on a form provided by the department, satisfying all the requirements for licensure in part 3 of these rules, and paying the requisite fee.
(2) An applicant that renews its license during the license renewal period shall submit to the department a completed application on a form provided by the department, together with the requisite fee.
(3) A wholesale distributor-broker seeking renewal shall submit an affidavit, at the time of the application for renewal that the applicant facilitates deliveries or trades for at least 50 qualified pharmacies and that each pharmacy holds a license in good standing as a pharmacy from the state in which it is located at the time of renewal.

PART 6. PRACTICE OF PHARMACY

R 338.582 Prescription drug labeling and dispensing.
Rule 82. (1) All labeling of prescription drugs must comply with the requirements of the code and sections 351 to 399f of the Federal Food, Drug, and Cosmetic Act, 21 USC 351 to 399f.
(2) All containers in which prescription medication is dispensed must bear a label that contains, at a minimum, all of the following information:
(a) Pharmacy name and address.
(b) Prescription number.
(c) Patient's name.
(d) Date the prescription was dispensed.
(e) Prescriber's name.
(f) Directions for use.
(g) The name of the medication and the strength, unless the prescriber indicates "do not label."
(h) The quantity dispensed, if applicable.
(i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates “do not label.”
(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed. This subrule does not apply if the prescriber indicates "do not label."
(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed must be noted on the prescription.
(5) This rule does not apply to pharmacy services provided in a medical institution.

R 338.583 Prescription drug receipts.
Rule 83. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt that contains all of the following information:

(a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."
(b) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."
(c) The strength of the drug, if significant, unless the prescribed indicates "do not label."
(d) The quantity dispensed, if applicable.
(e) The name and address of the pharmacy.
(f) The serial number of the prescription.
(g) The date the prescription was dispensed.
(h) The name of the prescriber.
(i) The name of the patient for whom the drug was prescribed.
(j) The price for which the drug was sold to the purchaser.
(2) Notwithstanding R 338.582, the information required in this rule must appear on either the prescription label or on a combination label and receipt.
(3) For prescription services that are covered by a third-party pay contract, the price included in the receipt is the amount paid by the patient.
(4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule in the automated data processing system or on the written prescription form and the retention of the form constitutes retaining a copy of the receipt. The physical presence of the prescription form in the pharmacy or the ability to retrieve the information from the automated data processing system constitutes compliance with the requirement of having the name and address of the pharmacy on the form.
(5) This rule does not apply to pharmacy services provided in a medical institution.

R 338.583a Pharmacy acquisition and distribution records.
Rule 83a. (1) A pharmacy must keep and make available for inspection all acquisition and distribution records for prescription and non-prescription drugs and devices, such as invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours.
(2) Acquisition and distribution records must include the following information:
(a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped.
(b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of.
(c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.

R 338.584 Noncontrolled prescriptions.
Rule 84. (1) A prescriber who issues a prescription for a noncontrolled prescription drug shall date the prescription; provide a manual signature on the prescription; and ensure that the prescription contains all of the following information:
(a) The full name of the patient for whom the drug is being prescribed.
(b) The prescriber’s preprinted, stamped, typed, or manually printed name and address.
(c) The drug name and strength, and dosage form if necessary.

(d) The quantity prescribed.
(e) The directions for use.
(f) The number of refills authorized.
(g) The date the prescription was issued.
(h) If the prescription is for an animal, then the species of the animal and the full name of the owner.
(2) A prescriber shall ensure that a prescription is legible and that the information specified in subrule (1)(c) to (h) of this rule is clearly separated.
(3) A prescriber shall not prescribe more than either of the following on a single prescription form as applicable:
(a) For a prescription prescribed in handwritten form, up to 4 prescription drug orders.
(b) For a prescription prescribed on a computer-generated form or a preprinted list or produced on a personal computer or typewriter, up to 6 prescription drug orders.
(4) A prescription is valid for 1 year from the date the prescription was issued.
(5) A pharmacy shall keep the original prescription record for 5 years. After 2 years from the date of the prescription's issue date, a pharmacy may make an electronic duplicate of the original non-controlled paper prescription, which becomes the original prescription. A pharmacy shall present a paper copy of the electronic duplicate of the prescription to an authorized agent of the board upon request.
(6) This rule does not apply to pharmacy services provided in a medical institution.

R 338.584a Electronic transmission of prescription; waiver of electronic transmission.
Rule 84a. (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 as 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 338.584.
(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 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 338.584 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 shall 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 also 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) Intention to cease practice within the next twelve months.
(B) 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 338.585 Customized patient medication package.
Rule 85. (1) A pharmacist may, with the consent of the patient, or the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package that is prepared by a pharmacist for a specific patient and that contains 2 or more prescribed solid oral dosage forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken. The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.
(2) If medication is dispensed in a CPMP, all of the following conditions must be met:
(a) Each CPMP must bear a readable label that states all of the following information:
(i) A serial number for the CPMP and a separate identifying serial number for each of the prescription orders for each of the drug products contained in the CPMP.
(ii) The name, strength, physical description, and total quantity of each drug product contained in the CPMP.
(iii) The name of the prescriber for each drug product.
(iv) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product in the CPMP.
(v) The date of the preparation of the CPMP.
(vi) An expiration date for the CPMP. The date must not be later than the earliest manufacturer's expiration date for any medication included in the CPMP or 60 days after the date of dispensing.
(vii) The name, address, and telephone number of the dispenser.

(viii) Any other information, statements, or warnings required for any of the drug products contained in the CPMP.
(b) A CPMP must be accompanied by any mandated patient information required under federal law. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.
(c) At a minimum, each CPMP must comply with the United States Pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, MCL 333.17706, for moisture permeation requirements for a class b single-unit or unit-dose container. Each container must be either non-reclosable or so designed as to show evidence of being opened. Each CPMP must comply with all of the provisions of the poison prevention packaging act of 1970, 15 USC 1471 to 1477.
(d) When preparing a CPMP, the dispenser shall consider any applicable compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may attend the simultaneous administration of the medications. Medications must not be dispensed in CPMP packaging in any of the following situations:
(i) The USP monograph or official labeling requires dispensing in the original container.
(ii) The drugs or dosage forms are incompatible with packaging components or each other.
(iii) The drugs are therapeutically incompatible when administered simultaneously.
(iv) The drug products require special packaging.
(e) If 2 medications have physical characteristics that make them indistinguishable from each other, then the medication must not be packaged together in the same CPMP.
(f) Medications that have been dispensed in CPMP packaging may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CPMP is changed, then a new appropriately labeled CPMP must be prepared for the patient.
(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed must be made and filed. At a minimum, each record must contain all of the following information:
(i) The name and address of the patient.
(ii) The serial number of the prescription order for each drug product contained in the CPMP.
(iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.
(iv) The date of preparation of the CPMP and the expiration date assigned.
(v) Any special labeling instructions.
(vi) The name or initials of the pharmacist who prepared the CPMP.

R 338.586 Prescription records; nonapplicability to inpatient medical institution service.
Rule 86. (1) Each prescription must be chronologically numbered, and the pharmacist performing final verification before dispensing must record, manually or electronically, the prescription number, dispensing date, and his or her initials at the time of the first filling at the pharmacy.

(2) If final product verification is completed by a pharmacy technician, both the initials of the pharmacy technician and delegating pharmacist must be recorded.
(3) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.
(4) This rule does not apply to pharmacy services provided in a medical institution.

R 338.587 Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.
Rule 87. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.
(2) A pharmacy may utilize a manual system of recording refills if the system complies with both of the following criteria:
(a) The amount and date dispensed must be entered on the prescription in an orderly fashion and the dispensing pharmacist initials the entry. If the pharmacist only initials and dates the prescription, then the full face amount of the prescription must be deemed dispensed.
(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.
(3) A pharmacy may utilize a uniform system of recording refills if the system complies with all of the following criteria:
(a) Records must be created and maintained in written form. All original and refill prescription information for a particular prescription appears on single documents in an organized format. The records are subject to inspection by the board or its agents.
(b) The following information for each prescription must be entered on the record:
(i) The prescription number.
(ii) The patient's name and address.
(iii) The prescriber's name.
(iv) The prescriber's federal drug enforcement administration (DEA) number, if appropriate.
(v) The number of refills authorized.
(vi) The "dispense as written" instructions, if indicated.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.
(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill. If a pharmacy technician performs final product verification, the identification of the delegating pharmacist and pharmacy technician must be recorded.
(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized

so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.
(d) The information required by subdivision (b) of this subrule must be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.
(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system complies with all of the following criteria:
(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:
(i) The prescription number.
(ii) The patient's name and address.
(iii) The prescriber's name.
(iv) The prescriber's federal DEA number, if appropriate.
(v) The number of refills authorized.
(vi) Whether the drug must be dispensed as written.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.
(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill. If a pharmacy technician performs final product verification, the identification of the delegating pharmacist and pharmacy technician must be recorded.
(b) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. A pharmacy shall keep the original prescription record on site for 5 years. After 2 years from the date of the prescription’s issue date, a pharmacy may make an electronic duplicate of the original non-controlled paper prescription, which will become the original prescription. The records are subject to inspection by the board or its agents. A procedure must be established to facilitate inspections.
(c) The required information must be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.
(d) The recording system must provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records.
(e) The recording system must have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trail for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other

required information must be made available to an authorized agent of the board upon request. The prescription data must be maintained for 5 years. Data older than 2 years must be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current 2 years must be readily retrievable on site and available for immediate review.
(f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.
(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall ensure continuity in the maintenance of records.
(h) The automated data processing system must be an integrated system that is capable of complying with all of the requirements of these rules.
(5) This rule does not apply to pharmacy services provided in a medical institution.
(6) Records that are created under subrule (2), (3) or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

R 338.588 Automated devices.
Rule 88. (1) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.
(2) An automated device may be used only in the following locations:
(a) A pharmacy, or at the same physical address as the pharmacy provided that the location of the automated device is owned and operated by the same legal entity as the pharmacy.
(b) A hospital.
(c) A county medical care facility.
(d) A hospice.
(e) A nursing home.
(f) Other skilled nursing facility as defined in section 20109(4) of the code, MCL 333.20109.
(g) An office of a dispensing prescriber.
(h) A location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, consistent with section 17760 of the code, MCL 333.17760.
(3) A pharmacy that operates an automated device under this section only to deliver a non-controlled drug or device directly to an ultimate user or health care provider shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be under the control of a pharmacist or his or her pharmacy personnel under the personal charge of a

pharmacist. A secured, lockable, and privacy enabled automated device located on the premise of the licensed pharmacy may be utilized as a means for a patient or an agent of the patient to pick up prescription medications.

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

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

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

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

(i) Manufacturer name and model.

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

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

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

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

(a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.
(b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the pharmacy for review by an agent of the board. The documentation must include at least all of the following information:
(i) Name and address of the pharmacy responsible for the operation of the automated device.
(ii) Name and address of the facility where the automated device is located.
(iii) Manufacturer name and model number.
(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.
(v) Policy and procedures for system operation that address, at a minimum, all of the following:
(A) Accuracy.
(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.
(F) Emergency procedures.
(G) Medication security.
(H) Quality assurance.
(I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.
(6) An automated device that is operated at a location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, must comply with section 17760 of the code, MCL 333.17760.
(7) Records and electronic data kept by automated devices must meet all of the following requirements:
(a) All events involving access to the contents of the automated devices must be recorded electronically.
(b) Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:
(i) The unique identifier of the automated device accessed.
(ii) Identification of the individual accessing the automated device.
(iii) The type of transaction.
(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.
(v) The name of the patient for whom the drug was ordered.
(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.
(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or

removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:
(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(j).
(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).
(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.
(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.
(e) The automated device is located in a dispensing prescriber's office.
(9) A copy of all policies and procedures related to the use of an automated device must be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

R 338.589 Professional responsibility; “caregiver” defined.
Rule 89. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code, MCL 333.17748, or from other lawful channels of distribution.
(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:
(a) The prescription appears to be improperly written.
(b) The prescription is susceptible to more than 1 interpretation.
(c) The pharmacist has reason to believe that the prescription could cause harm to the patient.
(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.
(3) A prescription drug must be dispensed only when the pharmacy is open and under the personal charge of a pharmacist.
(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate to the patient, or the patient’s caregiver, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient’s care. All of the following provisions apply to communicating medication safety and effectiveness information:
(a) The information must be communicated orally and in person, except when the patient or patient’s caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed or electronic/digital material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.
(b) The information must be provided with each prescription for a drug not previously prescribed for the patient.

(c) If the pharmacist deems it appropriate, the information must be provided with prescription refills.
(d) The information must be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.
(5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code, MCL 333.16215, and under the personal charge of the delegating pharmacist, except as provided in R 338.486. A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person shall do all of the following:
(a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.
(b) Before delegating an act, task, or function, make a determination that the delegate has the necessary knowledge and skills to safely and competently complete the act, task, or function.
(c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.
(d) Supervise and evaluate the performance of the delegatee.
(e) Provide remediation of the performance of the delegatee if indicated.
(6) A delegating pharmacist shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

R 338.590 Hospice emergency drug box.
Rule 90. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes pursuant to the provisions of section 17746 of the code, MCL 333.17746, shall establish drug boxes that are in compliance with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall ensure that the hospice has developed policies and procedures that require all of the following:
(a) Maintenance by the hospice of a drug box exchange log that accounts for the hospice's receipt of the boxes from the pharmacy, assignment of the boxes to registered nurses or physicians' assistants, and return of the boxes to the pharmacy for restocking.
(b) A procedure to ensure that the drug boxes are inspected at least weekly to determine if they have expired or have been opened.
(c) Procedures for the storage and control of a drug box while it is assigned to, and being used by, the prescriber, a registered nurse, or a physician's assistant.
(d) A procedure for implementing the hospice medical director's responsibility for ensuring that prescriptions for drugs removed from the drug boxes are obtained from an appropriate prescriber.
(2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.
(3) The drugs contained in each drug box must be listed inside the front cover of the box. Each box must be equipped with only 1 nonreusable, tamper-evident seal or sealing

system which is a color that designates that the box has not been opened and several nonreusable, tamper-evident seals or sealing systems which are a different color that designates that the box has been opened.
(4) A drug box must be numbered. A permanent record of all drug boxes must be maintained at the pharmacy.
(5) A label that contains all of the following information must be attached to the drug box so that it is visible from the outside of the box:
(a) The name and address of the pharmacy.
(b) The name and address of the hospice.
(c) The name of the pharmacist who last inspected and restocked the drug box.
(d) The date the drug box was last restocked.
(e) The date on which the drug box must be returned to the pharmacy for the replacement of expired drugs.
(f) The number of the drug box.
(6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreusable, tamper-evident seal or sealing system which is the color that designates that the box has not been opened.
(7) A drug box must be kept in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, prescriber, registered nurse, or physician's assistant. The box must be stored under conditions that will maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment and to the drug box must be limited to individuals who are authorized to stock the drug box or to dispense drugs from the drug box on the order of an appropriate prescriber.
(8) The drug box must remain sealed at all times, except when in use. All drugs removed from the box must be recorded on a medication use form. After completing the form, the physician, registered nurse or physician's assistant who removed the drug must place the form in the drug box and seal the box with a nonreusable, tamper-evident seal or sealing system which is a color that designates that the box has been opened.
(9) Each drug box under the control of the pharmacy must be examined at least weekly to ensure that the seal which designates that the box has not been opened is still intact and the expiration date has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box must be returned to the pharmacy. The written prescription for all drugs that have been administered from the drug box must accompany the drug box when it is returned to the pharmacy after opening.
(10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record must contain all of the following information:
(a) The number of the box.
(b) The name of the hospice to which the box is released.
(c) The date the box is released to the hospice.
(d) The name and signature of the pharmacist who releases the box to the hospice.
(e) The expiration date assigned.
(f) The date the box is returned to the pharmacy for restocking.
(g) The name and signature of the pharmacist who received the box for restocking.
(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the appropriate prescriber or medical director of the hospice. The pharmacist shall note that the prescriptions were

dispensed from the hospice drug box on the back of the prescriptions. The prescriptions must be filed in the same manner as other prescriptions are maintained at the pharmacy.