STATE OF MICHIGAN
JOCELYN BENSON, SECRETARY OF STATE
DEPARTMENT OF STATE
LANSING

May 28, 2024

NOTICE OF FILING

ADMINISTRATIVE RULES

To: Secretary of the Senate
Clerk of the House of Representatives
Joint Committee on Administrative Rules
Michigan Office of Administrative Hearings and Rules (Administrative Rule #22-006-LR)
Legislative Service Bureau (Secretary of State Filing #24-05-04)
Department of Licensing and Regulatory Affairs

In accordance with the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6, this is to advise you that the Michigan Office of Administrative Hearings and Rules filed Administrative Rule #2022-006-LR (Secretary of State Filing #24-05-04) on this date at 12:51 P.M. for the Department of Licensing and Regulatory Affairs entitled, "Pharmacy – Controlled Substances".

These rules become effective immediately after 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.

Sincerely,

Jocelyn Benson
Secretary of State

Lashana Threlkeld, Departmental Supervisor
Office of the Great Seal

Enclosure

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
SUZANNE SONNEBORN
EXECUTIVE DIRECTOR

MARLON I. BROWN, DPA
DIRECTOR

May 28, 2024

The Honorable Jocelyn Benson
Secretary of State
Office of the Great Seal
Richard H. Austin Building – 1st Floor
430 W. Allegan
Lansing, MI 48909

Dear Secretary Benson:

Re: Administrative Rules – Michigan Office of Administrative Hearings and Rules
Administrative Rules #: 2022-6 LR

The Michigan Office of Administrative Hearings and Rules received administrative rules, dated March 5, 2024 for the Department of Licensing and Regulatory Affairs **"Pharmacy - Controlled Substances".** We are transmitting these rules to you pursuant to the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6.

Sincerely,

Michigan Office of Administrative Hearings and Rules

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

MARLON I. BROWN, DPA
ACTING DIRECTOR

CERTIFICATE OF ADOPTION

By authority conferred on the Director of the Department of Licensing and Regulatory Affairs and 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, R 338.3102, R 338.3104, R 338.3111, R 338.3132, R 338.3135, R 338.3141, R 338.3143, R 338.3145, R 338.3151, R 338.3153, R 338.3153a,R 338.3154, R 338.3161, R 338.3161a, R 338.3162, R 338.3162a, R 338.3162b, R 338.3162c, R 338.3162d, R 338.3164, R 338.3165, R 338.3166, R 338.3167, R 338.3170, R 338.3181, R 338.3183, and R 338.3185, of the Michigan Administrative Code are amended, and R 338.3137 and R 338.3163 are rescinded.

Date: 02/01/2024

Adopted by: Marlon I. Brown

Marlon I. Brown, DPA
Acting Director
Department of Licensing and Regulatory Affairs

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
SUZANNE SONNEBORN
EXECUTIVE DIRECTOR

MARLON I. BROWN, DPA
DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated March 5, 2024, in which the Department of Licensing and Regulatory Affairs proposes to modify a portion of the Michigan Administrative Code entitled "Pharmacy—Controlled Substances" by:

- Amending R 338.3101, R 338.3102, R 338.3104, R 338.3111, R 338.3132, R 338.3135, R 338.3141, R 338.3143, R 338.3145, R 338.3151, R 338.3153, R 338.3153a, R 338.3154, R 338.3161, R 338.3161a, R 338.3162, R 338.3162a, R 338.3162b, R 338.3162c, R 338.3162d, R 338.3164, R 338.3165, R 338.3166, R 338.3167, R 338.3170, R 338.3181, R 338.3183, and R 338.3185.
- Rescinding R 338.3137 and R 338.3163.

The Legislative Service Bureau has approved the proposed rules as to form, classification, and arrangement.

I approve the rules as to legality pursuant to the Administrative Procedures Act, MCL 24.201 *et seq.* and Executive Order No. 2019-6. In certifying the rules as to legality, I have determined that they are within the scope of the authority of the agency, do not violate constitutional rights, and are in conformity with the requirements of the Administrative Procedures Act.

Dated: March 11, 2024

Michigan Office of Administrative Hearings and Rules

By: Ashlee N. Lynn

Ashlee N. Lynn,
Attorney

LEGISLATIVE SERVICE BUREAU
Since 1941

Legal Division

Kevin H. Studebaker, Director

CERTIFICATE OF APPROVAL

On behalf of the Legislative Service Bureau, and as required by section 45 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.245, I have examined the proposed rules of the Department of Licensing and Regulatory Affairs dated March 5, 2024, amending R 338.3101, R 338.3102, R 338.3104, R 338.3111, R 338.3132, R 338.3135, R 338.3141, R 338.3143, R 338.3145, R 338.3151, R 338.3153, R 338.3153a, R 338.3154, R 338.3161, R 338.3161a, R 338.3162, R 338.3162a, R 338.3162b, R 338.3162c, R 338.3162d, R 338.3164, R 338.3165, R 338.3166, R 338.3167, R 338.3170, R 338.3181, R 338.3183, and R 338.3185, and rescinding R 338.3137 and R 338.3163 of the Department's rules entitled "Pharmacy – Controlled Substances." I approve the rules as to form, classification, and arrangement.

Dated: March 8, 2024

LEGISLATIVE SERVICE BUREAU

By _____

Rachel M. Hughart,
Legal Counsel

Michigan Legislature
124 W. Allegan Street, 3rd Floor • P.O. Box 30036 • Lansing, MI 48909-7536 • (517) 373-9425 • Fax: (517) 373-5642

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY – CONTROLLED SUBSTANCES

Filed with the secretary of state on May 28, 2024

These rules become effective immediately after 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 and 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, R 338.3102, R 338.3104, R 338.3111, R 338.3132, R 338.3135, R 338.3141, R 338.3143, R 338.3145, R 338.3151, R 338.3153, R 338.3153a, R 338.3154, R 338.3161, R 338.3161a, R 338.3162, R 338.3162a, R 338.3162b, R 338.3162c, R 338.3162d, R 338.3164, R 338.3165, R 338.3166, R 338.3167, R 338.3170, R 338.3181, R 338.3183, and R 338.3185, of the Michigan Administrative Code are amended, and R 338.3137 and R 338.3163 are rescinded, as follows:

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

(a) "ASAP" means the American Society for Automation in Pharmacy.

(b) "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.

(c) "Board" means the board of pharmacy.

(d) "CMS" means the United States Centers for Medicare and Medicaid Services.

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

(f) "CSA" means the controlled substances act, Public Law 91-513.

(g) "DEA" means the United States Drug Enforcement Administration.

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

(i) "Electronic signature" means an electronic sound, symbol, or process attached to or 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 that is only available for use by the intended individual and ensures nonrepudiation so that the signature may not be rejected based on its validity.

(j) "FDA" means the United States Food and Drug Administration.

(k) "FDCA" means the Federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399g.

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 that is licensed under section 7303 of the code, MCL 333.7303.

(c) "MAPS" means the Michigan automated prescription system.

(d) MAPS claim form" means a form determined by the department that is in the format and includes the information as specified by the ASAP 5.0 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.

(e) "Medical institution" means that term as defined in R 338.486.

(f) "NDC" means a national drug code number that identifies the labeler, product, and package size and is assigned to each drug product listed under section 510 of the FDCA, 21 USC 360.

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

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

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

(iv) One 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) A tribal government identification number obtained from a tribal government issued identification.

(E) 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.

(i) "Positive identification" means identification that includes a photograph of an individual in addition to the individual's date of birth. Positive identification includes an identification card issued by a governmental agency.

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

(a) "Readily retrievable" means a record that is maintained and can be separated from all other records within 48 hours and is a listed controlled substance that 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.

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 CSA, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15, except for the following:

(a) Drugs or other substances scheduled, rescheduled, or descheduled by this state's laws enacted after January 6, 2022.

(b) Drugs listed in subrule (3) of this rule, which are scheduled differently than scheduled in 21 CFR 1308.11 to 1308.15.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.ecfr.gov/current/title-21/chapter-II/part-1308, 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 designated as a schedule 1, 2, 3, 4, or 5 drug, as follows:

Drug or Substance	1	2	3	4	5
(a) Synthetic cannabinoid: Includes a material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules 2 to 5, is not approved by the FDA as a drug, and contains a 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) A 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 an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include,	x				

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) A 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 an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-175 and JWH-184. (iii) A 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 an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-370 and JWH-030. (iv) A 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 an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-176. (v) A 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 an extent and whether or not substituted on the phenyl ring to an 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) A 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, whether or not substituted on the cyclohexyl ring to an extent. Examples of this structural class include, but are not limited to, CP-47,497 (and homologues(analogs)), cannabicyclohexanol, and CP-55,940.					

(vii) A 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 an extent and whether or not substituted on the phenyl ring to an 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) A compound containing a 11-hydroxy-Δ8-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) A compound containing a 3-(1-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 an extent. Examples of this structural class include, but are not limited to, AM-1248. (x) A synthetic chemical compound that is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring cannabinoids that is not listed in schedules 2 through 5 and is not approved by the FDA as a drug.					
(b) Synthetic cathinone: Includes a material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules 2 through 5, is not approved by the FDA as a drug, and contains a 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) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a monocyclic or fused polycyclic ring system and a substitution at the nitrogen atom by an alkyl group, cycloalkyl group, or incorporation into a heterocyclic structure. Examples of this structural class include, but are not limited to, dimethylcathinone, ethcathinone, and alpha-pyrrolidinopropiophenone.	x				

(ii) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a monocyclic or fused polycyclic ring system and a substitution at the 3-position carbon with an alkyl, haloalkyl, or alkoxy group. An example of this structural class includes, but is not limited to, naphyrone. (iii) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a monocyclic or fused polycyclic ring system and a substitution at a position of the ring system with an alkyl, haloalkyl, halogen, alkylenedioxy, or alkoxy group, whether or not further substituted at a position on the ring system to an extent. Examples of this structural class include, but are not limited to, mephedrone, methylone, and 3-fluoromethylone.					
(c) 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 except for both the following: (i) 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: (A) May lawfully be sold over the counter without a prescription under federal law. (B) Is labeled and marketed in a manner consistent with the pertinent over-the-counter tentative final or final monograph. (C) Is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse. (D) Is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement. (E) The drug product is 1 of the following: (I) 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. (II) An anorectal preparation containing not more than 5% ephedrine. (ii) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria: (A) 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 FDA and contains no other controlled substance.					x

(B) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids. (C) Is packaged with a prominent label securely affixed to each package that includes all of the following: (I) The amount in milligrams of ephedrine in a serving or dosage unit. (II) The amount of the food product or dietary supplement that constitutes a serving or dosage unit. (III) 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. (IV) That improper use of the product may be hazardous to an individual's health.					
(d) Isomers: The definition of the term "isomer" used in 21 CFR 1308.11, schedule 1, is modified to include any optical, positional, or geometric isomer. The definition of "isomer" used in 21 CFR 1308.12 to 1308.15, schedules 2 to 5, remains as set forth in 21 CFR 1300.	x				
(e) Marijuana: As that term is defined in section 3 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27953, and pharmaceutical-grade cannabis, as that term is defined in section 8105 of the code, MCL 333.8105, if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the code but only for the purpose of treating a debilitating medical condition, as that term is defined in section 3 of the Michigan Medical Marihuana Act, 2008 IL 1, MCL 333.26423, and as allowed under the code.		x			
(f) Salvia divinorum: All parts of the plant presently classified botanically as Salvia divinorum, whether growing or not; the leaves and seeds of that plant; an extract from a part of that plant; and every compound, salt, derivative, mixture, or preparation of that plant or its leaves, seeds, or extracts.	x				
(g) Salvinorin A	x				
(h) Tianeptine sodium: By whatever official, common, usual, chemical, or brand name designated.		x			

PART 3. LICENSES

R 338.3132 Controlled substance license.

Rule 32. (1) A person that manufactures, distributes, prescribes, or dispenses a controlled substance in this state or 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 required fee.

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, an applicant's license must be verified by the licensing agency of a state where the applicant holds or has ever held a controlled substance license. This includes, but is not limited to, showing proof of 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 listed 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 submitted to the department with the application for licensure and filed and approved by the FDA and the DEA under 21 CFR 1301.18.

(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 that 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 that 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 a 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 that 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 under section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility, as that term is 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 for the address where the drugs are stored. If a controlled substance is stored in an emergency kit, a controlled substance license solely for the emergency kit is not required by this rule.

(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 if the license issued under article 15 of the code, MCL 333.16101 to 333.18838 is renewed and the controlled substance license is renewed for an equal number of years.

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with the 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 contains the following information:

(i) The following investigator information:

(a) Name, address, and DEA registration number, if any.

(b) Institutional affiliation.

(c) Qualifications, including a curriculum vitae and an appropriate list of publications.

(ii) The following research project information:

(a) Title of project.

(b) Statement of the purpose.

(c) Name of the controlled substance or substances involved and the amount of each needed.

(d) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(e) Location where the research will be conducted.

(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion.

(g) If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(iii) The following authorization information:

(a) Institutional approval.

(b) Approval of a Human Research Committee for human studies.

(c) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(d) Indication of an approved funded grant (number), if any.

(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 the 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 the 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 contains the following information:

(i) The following investigator information:

(a) Name, address, and DEA registration number, if any.

(b) Institutional affiliation.

(c) Qualifications, including a curriculum vitae and an appropriate list of publications.

(ii) The following chemical analysis project information:

(a) Title of project.

(b) Statement of the purpose.

(c) Name of the controlled substance or substances involved and the amount of each needed.

(d) Description of the chemical analysis and instructional activity to be conducted, and the duration of the project.

(e) Location where the chemical analysis will be conducted.

(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143.

(g) If the investigator desires to manufacture any controlled substance for analytical or instructional purposes, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(iii) The following authorization information:

(a) Institutional approval.

(b) Approval of a Human Research Committee for human studies.

(c) Indication of an approved funded grant (number), if any.

(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 a 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 or renewing a controlled substance license shall complete a training in opioids and controlled substances awareness before applying for the license or renewal. The training must meet the following standards:

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

(i) Utilizing the MAPS.

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

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

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) A prescriber or dispenser may 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 subrule (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, the individual shall provide an acceptable proof of completion of training, including 1 of the following:

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

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

(4) An individual who has been issued a controlled substance license under 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 a 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 the applicant provides proof of having completed the controlled substance training.

(5) Except as exempted under subrule (6) of this rule, veterinarians and 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 a controlled substance training. The training must be taken 1 time during the current license cycle and cover all of the following topics:

(a) Use of opioids and other controlled substances.

(b) Integration of treatments.

(c) Alternative treatments for pain management.

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

(e) The stigma of addiction.

(f) Utilizing the MAPS.

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

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

(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 Rescinded.

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) Within 45 days after 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 individual is identified and action is taken against the responsible individual, 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 non-controlled 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 that is licensed by the department under section 7303 or 17748 of the code, MCL 333.7303, or 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 reasonably should know, has a substance use disorder, as that term is defined in section 1100d of the mental health code, 1974 PA 258, MCL 330.1100d. 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 is currently under sentence for that conviction.

(2) A licensee shall not delegate, under 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, the licensee shall make an exact count or measure of the contents.

(b) If the substance is listed in schedule 3, 4, or 5, the licensee shall estimate the count or measure of the contents, but if the container holds more than 1,000 dosage units, 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 the licensee first engages in the activity covered by the license, including a change of a pharmacist in charge. The beginning inventory record for a licensed location must be maintained at the licensed location and a copy must be forwarded to the department on 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 must 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 that was not previously listed in a 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. The substance must be included in each subsequent inventory taken.

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

Rule 53. (1) For 2 years, a licensee shall maintain in the pharmacy for review by the department, an agency, or the board, all records for controlled substances, including invoices and acquisition records 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 initial or electronically initial the invoice and indicate the date that the controlled substances are received.

(2) A licensee shall maintain in the pharmacy for review by the department, an agency, or the board, patient sales receipts and dispensing records as follows:

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

(b) A licensee shall keep a record, which may be electronic, of all controlled substances dispensed by the licensee.

(c) A licensee that prescribes controlled substances shall keep a record separate from the patient chart that 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.

(d) 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.

(3) A licensee shall keep the original prescription record on-site for 5 years after the last date of dispensing. However, 2 years after the last date of dispensing, a licensee may make an electronic duplicate of the original paper prescription, which becomes the original prescription.

(4) A licensee shall maintain records of controlled substances distributed to another licensee that must include all of the following information and be maintained in the appropriate file described in subrule (1)(b) of this rule or in a separate record that is available for inspection:

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

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

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

(d) Date the controlled substances were distributed.

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

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, a pharmacist may dispense the controlled substance for administration to the inpatient if all of the following conditions are met:

(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 after 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 that becomes the original order. If a licensee maintains patient records electronically, a printed copy must be immediately available for a current inpatient and within 48 hours on request of an authorized agent of the board for a patient discharged in the last 5 years.

R 338.3154 Medication records in medical institutions.

Rule 54. (1) A patient's chart must 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 listed 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 it is 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) This subrule 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, 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 responsible for the operation of the automated device.

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

(c) The name and address of the facility where the automated device is located.

(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 if 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 medication from the automated device for immediate patient administration, except in the following situations where a pharmacist shall review the orders and authorize 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 stocked or restocked in the automated device.

(vii) Any 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 completed electronically.

(j) If the pharmacist delegates the stocking of the 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 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 must 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, and telephone number or pager number, and professional designation that is either written on the prescription or stored in the pharmacy's automated data processing system.

(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 complies if it contains 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, the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance listed in schedules 2 to 5 must 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, however, under sections 16106 and 17744 of the code, MCL 333.16106 and 333.17744, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who dispenses a controlled substance under a prescription not prepared in the form required by these rules is liable under the code.

(4) If the controlled substance prescription or order in a medical institution is issued under delegation, the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee must 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.

R 338.3161a. Exception to bona fide prescriber-patient relationship; alternative requirements.

Rule 61a. (1) Except as provided in subrule (2) of this rule and for a patient who is under the care of a hospice, a bona fide prescriber-patient relationship is required before a licensed prescriber may prescribe a controlled substance listed in schedules 2 to 5.

(2) Under 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 change in medical condition, and provides documentation in the patient's medical record consistent with 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 consistent with 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 subdivisions (a) and (b) of this subrule in compliance with R 325.45377, as applicable, and provides documentation in the patient's medical record consistent with medically accepted standards of care.

(d) The prescriber is prescribing for a patient for whom the tasks listed in subdivisions (a) and (b) of this subrule are 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 consistent with medically accepted standards of care.

(e) The prescriber is treating a patient in a medical emergency. As used in 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 that is regulated by section 17742a of the code, MCL 333.17742a, and that 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 must 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 if the individual is not known to the pharmacist or pharmacy employees, except if positive identification is not available and a pharmacist, who in exercising 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 under section 503 of the FDCA, 21 USC 353, under 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 under 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 must 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) Effective on January 1, 2023 prescribers shall, unless an exception under section 17754a of the code, MCL 333.17754a, applies, electronically transmit a prescription 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 17754a of the code, MCL 333.17754a, are met.

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

(3) 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 CMS.

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

(ii) 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 CMS waiver for electronic transmission of prescriptions for controlled substances, whichever is more.

(B) The prescriber has or intends within the next 12 months to no longer regularly practice their licensed profession for financial gain or as a means of livelihood.

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

(iii) The prescriber issues prescriptions from a not-for-profit medical clinic that provides free or low-cost services to the public.

(4) A waiver is valid for 2 years and applies 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, or 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 this 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. As used in this subdivision, all of the following apply:

(i) An identification number, as specified in R 338.3102(h)(iv)(A) to (E), 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(h)(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 the prescription is issued.

(k) The date the prescription is filled.

(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 the dispensed controlled substance, 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, a patient's representative, or veterinarian's client is correct.
(3) As used in this rule, R 338.3162c, and R 338.3162d, "dispense" or "dispensing" means the preparation, compounding, packaging, or labeling of a controlled substance along with delivery of the controlled substance under 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, "patient" means 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 5.0 Standard for Prescription Drug Monitoring Programs.
(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and 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 must be made in writing to the department.
(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if the pharmacist, dispensing prescriber, or veterinarian demonstrates an inability to report as required by R 338.3162b and agrees in writing to report the data to the department or the department's contractor by submitting a completed MAPS claim form 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 online 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 that 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. If a pharmacist, pharmacy, dispensing prescriber, or veterinarian receives notification of an error in data reporting, the 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 after being notified of the error.

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian that 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.

R 338.3163 Rescinded.

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 if all 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 patient.

(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 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 under 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, 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) After authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall comply with all of the following within 7 days:

(a) The prescriber shall deliver to the dispensing pharmacist a written prescription postmarked within 7 days after the date the prescription was dispensed, or electronically transmit the prescription under 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) After the dispensing pharmacist receives the prescription the pharmacist shall attach the prescription to the oral order that was earlier reduced to writing.

(c) The pharmacy shall notify the department if the prescriber fails to deliver to the pharmacy 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 under 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 notes 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 an additional quantity of the drug beyond 72 hours without a new prescription.

(f) The pharmacy has 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 listed 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 under 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 listed in schedule 2, if filled, must be filled not later than 30 days after the date 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 after 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 6 months after 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, 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 another substance listed in schedule 5 are distributed at retail to the same purchaser in a 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, the pharmacist shall affix a label to the container that holds the substance that includes all the following:

(a) The date the controlled substance was dispensed.

(b) The pharmacist's name.

(c) The name and address of the pharmacy 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 maintained for 5 years after 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 of the medication as determined by the pharmacist.

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of the prescriber's professional practice may dispense, 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 the veterinarian's 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 the dispenser's 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 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 distributed by the dispenser under this rule are more than 5% of the total number of dosage units of all controlled substances distributed and dispensed by the dispenser during the 12-month period, the dispenser shall obtain a license to distribute controlled substances.

R 338.3183 Distribution to suppliers.

Rule 83. (1) An individual who is lawfully in possession of a controlled substance that is listed in a schedule may return the substance to the individual who gave the person the substance or to the manufacturer of the substance without obtaining a license to distribute. The individual 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 of the individual who distributes the substance.

(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 state-controlled substances license to the department. The transfer of the controlled substances is subject to approval by the DEA under 21 CFR 1301.52 and written notification must be provided to the department 15 days before the controlled substances are transferred.

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