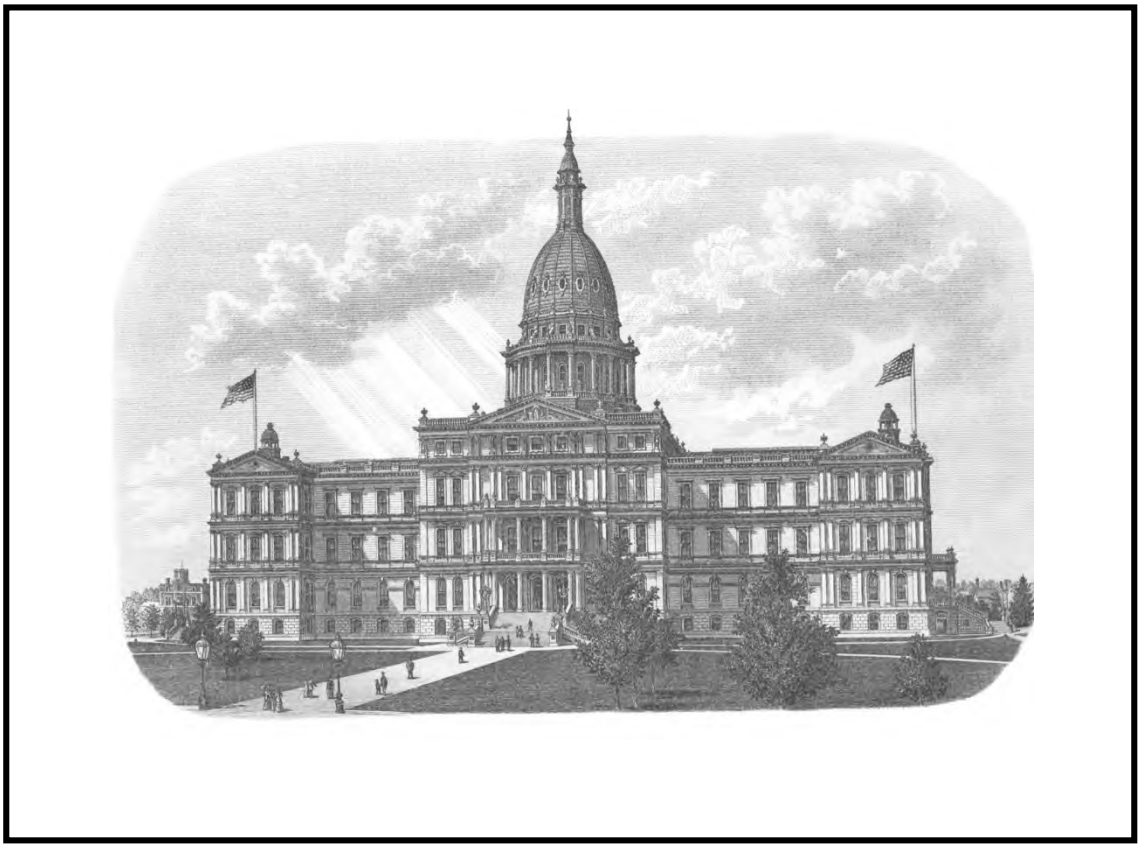
Michigan Register

Issue No. 10 – 2024 (Published June 15, 2024)



GRAPHIC IMAGES IN THE

MICHIGAN REGISTER

COVER DRAWING

Michigan State Capitol:

This image, with flags flying to indicate that both chambers of the legislature are in session, may have originated as an etching based on a drawing or a photograph. The artist is unknown. The drawing predates the placement of the statue of Austin T. Blair on the capitol grounds in 1898.

(Michigan State Archives)

PAGE GRAPHICS

Capitol Dome:

The architectural rendering of the Michigan State Capitol's dome is the work of Elijah E. Myers, the building's renowned architect. Myers inked the rendering on linen in late 1871 or early 1872. Myers' fine draftsmanship, the hallmark of his work, is clearly evident.

Because of their size, few architectural renderings of the 19th century have survived. Michigan is fortunate that many of Myers' designs for the Capitol were found in the building's attic in the 1950's. As part of the state's 1987 sesquicentennial celebration, they were conserved and deposited in the Michigan State Archives.

(Michigan State Archives)

East Elevation of the Michigan State Capitol:

When Myers' drawings were discovered in the 1950's, this view of the Capitol – the one most familiar to Michigan citizens – was missing. During the building's recent restoration (1989-1992), this drawing was commissioned to recreate the architect's original rendering of the east (front) elevation.

(Michigan Capitol Committee)

Michigan Register

Published pursuant to § 24.208 of
The Michigan Compiled Laws

Issue No. 10— 2024
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documents filed from May 1, 2024 to June 1, 2024)

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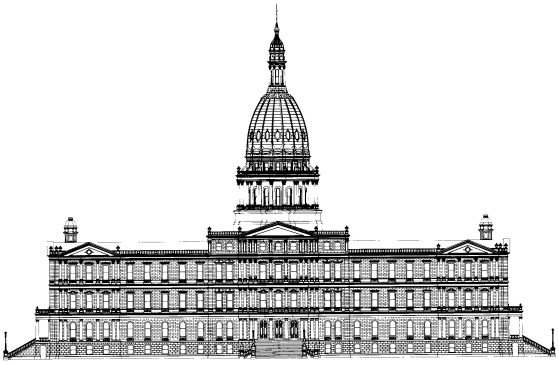
Katie Wienczewski, Administrative Rules Division Director, Michigan Office of Administrative Hearings and Rules; Deidre O'Berry, Administrative Rules Specialist for Operations and Publications.

Gretchen Whitmer, Governor



Garlin Gilchrist, Lieutenant Governor

PREFACE

PUBLICATION AND CONTENTS OF THE MICHIGAN REGISTER

The Michigan Office of Administrative Hearings and Rules publishes the *Michigan Register*.

While several statutory provisions address the publication and contents of the *Michigan Register*, two are of particular importance.

24.208 Michigan register; publication; cumulative index; contents; public subscription; fee; synopsis of proposed rule or guideline; transmitting copies to office of regulatory reform.

Sec. 8.

(1) The office of regulatory reform shall publish the Michigan register at least once each month. The Michigan register shall contain all of the following:

(a) Executive orders and executive reorganization orders.

(b) On a cumulative basis, the numbers and subject matter of the enrolled senate and house bills signed into law by the governor during the calendar year and the corresponding public act numbers.

(c) On a cumulative basis, the numbers and subject matter of the enrolled senate and house bills vetoed by the governor during the calendar year.

(d) Proposed administrative rules.

(e) Notices of public hearings on proposed administrative rules.

(f) Administrative rules filed with the secretary of state.

(g) Emergency rules filed with the secretary of state.

(h) Notice of proposed and adopted agency guidelines.

(i) Other official information considered necessary or appropriate by the office of regulatory reform.

(j) Attorney general opinions.

(k) All of the items listed in section 7(m) after final approval by the certificate of need commission under section 22215 of the public health code, 1978 PA 368, MCL 333.22215.

(2) The office of regulatory reform shall publish a cumulative index for the Michigan register.

(3) The Michigan register shall be available for public subscription at a fee reasonably calculated to cover publication and distribution costs.

(4) If publication of an agency's proposed rule or guideline or an item described in subsection (1)(k) would be unreasonably expensive or lengthy, the office of regulatory reform may publish a brief synopsis of the proposed rule or guideline or item described in subsection (1)(k), including information on how to obtain a complete copy of the proposed rule or guideline or item described in subsection (1)(k) from the agency at no cost.

(5) An agency shall electronically transmit a copy of the proposed rules and notice of public hearing to the office of regulatory reform for publication in the Michigan register.

4.1203 Michigan register fund; creation; administration; expenditures; disposition of money received from sale of Michigan register and amounts paid by state agencies; use of fund; price of Michigan register; availability of text on internet; copyright or other proprietary interest; fee prohibited; definition.

Sec. 203.

(1) The Michigan register fund is created in the state treasury and shall be administered by the office of regulatory reform. The fund shall be expended only as provided in this section.

(2) The money received from the sale of the Michigan register, along with those amounts paid by state agencies pursuant to section 57 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.257, shall be deposited with the state treasurer and credited to the Michigan register fund.

(3) The Michigan register fund shall be used to pay the costs of preparing, printing, and distributing the Michigan register.

(4) The department of management and budget shall sell copies of the Michigan register at a price determined by the office of regulatory reform not to exceed the cost of preparation, printing, and distribution.

(5) Notwithstanding section 204, beginning January 1, 2001, the office of regulatory reform shall make the text of the Michigan register available to the public on the internet.

(6) The information described in subsection (5) that is maintained by the office of regulatory reform shall be made available in the shortest feasible time after the information is available. The information described in subsection (5) that is not maintained by the office of regulatory reform shall be made available in the shortest feasible time after it is made available to the office of regulatory reform.

(7) Subsection (5) does not alter or relinquish any copyright or other proprietary interest or entitlement of this state relating to any of the information made available under subsection (5).

(8) The office of regulatory reform shall not charge a fee for providing the Michigan register on the internet as provided in subsection (5).

(9) As used in this section, "Michigan register" means that term as defined in section 5 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.205.

CITATION TO THE MICHIGAN REGISTER

The *Michigan Register* is cited by year and issue number. For example, 2024 MR 1 refers to the year of issue (2024) and the issue number (1).

CLOSING DATES AND PUBLICATION SCHEDULE

The deadlines for submitting documents to the Michigan Office of Administrative Hearings and Rules for publication in the *Michigan Register* are the first and fifteenth days of each calendar month, unless the submission day falls on a Saturday, Sunday, or legal holiday, in which event the deadline is extended to include the next day which is not a Saturday, Sunday, or legal holiday. Documents filed or received after 5:00 p.m. on the closing date of a filing period will appear in the succeeding issue of the *Michigan Register*.

The Michigan Office of Administrative Hearings and Rules is not responsible for the editing and proofreading of documents submitted for publication.

Documents submitted for publication should be delivered or mailed in an electronic format to the following address: MICHIGAN REGISTER, Michigan Office of Administrative Hearings and Rules, Ottawa Building – Second Floor, 611 W. Ottawa Street, Lansing, MI 48933.

RELATIONSHIP TO THE MICHIGAN ADMINISTRATIVE CODE

The *Michigan Administrative Code* (1979 edition), which contains all permanent administrative rules in effect as of December 1979, was, during the period 1980-83, updated each calendar quarter with the publication of a paperback supplement. An annual supplement contained those permanent rules, which had appeared in the 4 quarterly supplements covering that year.

Quarterly supplements to the Code were discontinued in January 1984, and replaced by the monthly publication of permanent rules and emergency rules in the *Michigan Register*. Annual supplements have included the full text of those permanent rules that appear in the twelve monthly issues of the *Register* during a given calendar year. Emergency rules published in an issue of the *Register* are noted in the annual supplement to the Code.

SUBSCRIPTIONS AND DISTRIBUTION

The *Michigan Register,* a publication of the State of Michigan, is available for public subscription at a cost of $400.00 per year. Submit subscription requests to: Michigan Office of Administrative Hearings and Rules, Ottawa Building –Second Floor, 611 W. Ottawa Street, Lansing, MI 48933. Checks Payable: State of Michigan. Any questions should be directed to the Michigan Office of Administrative Hearings and Rules (517) 335-2484.

INTERNET ACCESS

The *Michigan Register* can be viewed free of charge on the website of the Michigan Office of Administrative Hearings and Rules – Administrative Rules Division: www.michigan.gov/ard.

Issue 2000-3 and all subsequent editions of the *Michigan Register* can be viewed on the Michigan Office of Administrative Hearings and Rules website. The electronic version of the *Register* can be navigated using the blue highlighted links found in the Contents section. Clicking on a highlighted title will take the reader to related text, clicking on a highlighted header above the text will return the reader to the Contents section.

Executive Director,
Michigan Office of Administrative Hearings and Rules

2024 PUBLICATION SCHEDULE

Issue No.	Closing Date for Filing or Submission Of Documents (5 p.m.)	Publication Date
1	January 1	February 1
2	January 15	February 15
3	February 1	March 1
4	February 15	March 15
5	March 1	April 1
6	March 15	April 15
7	April 1	May 1
8	April 15	May 15
9	May 1	June 1
10	May 15	June 15
11	June 1	July 1
12	June 15	July 15
13	July 1	August 1
14	July 15	August 15
15	August 1	September 1
16	August 15	September 15
17	September 1	October 1
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20	October 15	November 15
21	November 1	December 1
22	November 15	December 15
23	December 1	January 1
24	December 15	January 15

CONTENTS

ADMINISTRATIVE RULES
FILED WITH THE SECRETARY OF STATE

MCL 24.208 states in part:

"Sec. 8. (1) The Office of Regulatory Reform shall publish the Michigan register at least once each month. The Michigan register shall contain all of the following:

* * *

(f) Administrative rules filed with the secretary of state."

ADMINISTRATIVE RULES

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, 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.	x				

(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-/\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) 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	x				

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. (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. (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					x

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.

ADMINISTRATIVE RULES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUREAU OF EPIDEMIOLOGY

DIVISION OF LIFECOURSE EPIDEMIOLOGY AND GENOMICS

MANDATORY REPORTING OF CHRONIC DISEASES

Filed with the secretary of state on May 1, 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 health and human services by sections 2221, 2226, 2233, and 5111 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, 333.2233, 333.5111, and section 8 of the critical health problems reporting act, 1978 PA 312, MCL 325.78)

R 330.131, R 330.132, R 330.133, R 330.134, R 330.135, and R 330.136 are added to the Michigan Administrative Code, as follows:

R 330.131 Definitions.

Rule 131. (1) As used in these rules:

(a) “Chronic disease registry” means the database maintained by the department that contains patient-level health information about individuals with a diagnosed chronic disease, including, but not limited to, diagnostic and demographic information.

(b) “Code” means the public health code, 1978 PA 368, MCL 333.1101 to 333. 25211.

(c) "Department" means the department of health and human services.

(d) “Director” means the director of the department.

(e) "Health information" means information about an individual, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental health or condition of an individual, and the provision of health care to an individual. Health information includes aggregate information if, in the opinion of the department, it could potentially lead to reidentification of an individual.

(f) “Health professional" means an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, to work as a physician, a physician's assistant, or a nurse practitioner.

(g) "Local health department" means a health department established under the provisions of part 24 of the code, MCL 333.2401 to 333.2498.

(h) "Public health investigation" means the collection of medical, epidemiologic, exposure, and other information to determine the cause of illness or disability, which is used to determine appropriate actions to prevent or mitigate additional illness or disability.

(i) “Report” means documents or data containing health information provided to the department consistent with this ruleset.

(2) A term defined in the code has the same meaning when used in these rules.

R 330.132 Reportable information.

Rule 132. (1) Health professionals and health facilities must provide reports to the department in a format that ensures the inclusion of all patient information, if available and applicable, as follows:

(a) Last and first name and middle initial.

(b) Sex.

(c) Race.

(d) Ethnicity.

(e) Birth date or age.

(f) Current residential address.

(g) Telephone number.

(h) If the individual is a minor, the name of the individual’s parent or guardian.

(i) Social security number.

(j) The date of symptom onset, if applicable.

(k) The date of diagnosis.

(l) The diagnosis, including diagnostic code.

(m) Prescribed medications, if they are available to the health professional or health facility, and the health professional or health facility is able to report them in the format prescribed by the department.

(n) Brief narrative of the patient’s signs and symptoms, clinical findings, results of other diagnostic tests, and clinical outcome, if available to the health professional or health facility.

(2) The reporting health professional shall provide the name, address, telephone, and other contact information, including, but not limited to, email communication, for the ordering physician or physicians as directed by the department.

(3) The reporting health facility shall provide the facility’s name, address, telephone, and other contact information, including, but not limited to, email communication, as directed by the department.

(4) Submitted reports must meet data quality, format, and timeliness standards prescribed by the department.

R 330.133 Reporting responsibilities.

Rule 133. (1) Health professionals and health facilities capable of reporting to the department via an electronic health record must do so on a real-time, ongoing basis.

(2) Health professionals and health facilities that do not submit reports consistent with subrule (1) of this rule shall provide reports to the department as follows:

(a) Reports must be made within 3 months following a request by the department or local health department.

(b) The department shall notify health professionals and health facilities when reports of a chronic disease must be submitted.

(3) Nothing in this rule should be construed to relieve a health professional or health facility from reporting to any other entity as required by state, federal, or local statutes or regulations or in accordance with accepted standard of practice, except that reporting in compliance with this rule satisfies the reporting requirements of section 5111 of the code , MCL 333.5111.

R 330.134 Chronic disease registry advisory board.

Rule 134. (1) The department shall create a chronic disease registry advisory board that convenes at the time and place instructed by the director and considers proposals and requests for the addition or removal of new reportable chronic diseases.

(2) The chronic disease registry advisory board shall consist of not less than 12 members appointed by the director as follows:

(a) One individual representing the Michigan Health and Hospital Association.

(b) Two individuals representing the department's public health administration.

(c) One individual representing a chronic disease organization.

(d) One individual representing a local health department.

(e) One individual representing the Michigan State Medical Society.

(f) One individual representing emergency medical services.

(g) One individual representing the chronic disease academic community.

(h) One individual representing a minority-serving community-based organization.

(i) One individual representing a tribal health agency.

(j) One individual representing a health system or hospital in this state.

(k) One individual representing the general public.

(3) In addition to those representatives named in subrule (2), the director may appoint additional representatives to the board.

(4) As directed by the department, members of the board shall maintain and adhere to the chronic disease registry advisory board's bylaws, including member term limits, member nominations, subcommittee formation, and other policies and procedures relevant to the board's ongoing operations.

(5) The board shall examine the public health need for the collection of this information and may request assistance from the department to inform their recommendation regarding the addition or removal of a chronic disease as needed. This information may include requesting supplementary information from the individual or party proposing the chronic disease, convening subject-matter experts or individuals with knowledge of the particular condition, or assembling ad-hoc subcommittees.

(6) The board shall release its recommendations, including whether a chronic disease should be made reportable, to the director of the department. The board may review or modify their recommendation at any time prior to the director's review. The director shall then approve, modify, or reject the recommendations of the board.

R 330.135 Investigation and quality assurance.

Rule 135. (1) The department, upon receiving a report under R 330.133, may request more information from the reporting entity. The reporting entity must provide the information to the department no later than 30 days after the request is made.

(2) The department shall consult with local health departments in the development of procedures for processing chronic disease reports and conducting follow-up investigations to ensure efficient, non-duplicative, and effective public health response.

(3) Requests by the department or local health departments for individual medical and epidemiologic information to validate the completeness and accuracy of reporting are specifically authorized. Persons or organizations that receive such requests must provide the information sought to the requesting organization promptly and no later than 30 days after the request is made.

(4) Health information from reported chronic disease cases shall be stored in a reasonably secure manner by the department.

R 330.136 Confidentiality of reports.

Rule 136. (1) To the maximum extent permitted by law, reports and health information collected under these rules are not public records and are exempt from disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(2) Reports and health information collected under this rule are medical records for the purpose of section 13(1)(l) of the freedom of information act, 1976 PA 442, MCL 15.243.

(3) Except as provided in subrule (5) of this rule, health information that is gathered in connection with an investigation is confidential and is not open to public inspection. All persons in possession of reports and health information collected under these rules shall maintain the confidentiality of reports and health information and shall not reveal the identity of any person.

(4) Records released to a legislative body must not contain information that identifies or could reasonably be expected to identify a specific individual.

(5) Information collected under these rules must be used for epidemiologic investigation and evaluation. The department and local health departments may release reports or information under any of the following conditions:

(a) The department receives written consent from the individual or consent from a minor's parent or legal guardian after requesting the release of information.

(b) As necessary for the department to carry out its duties designated by the code.

(c) If necessary for the purpose of research designed to contribute to generalizable knowledge, with documented approval by the department's institutional review board.

ADMINISTRATIVE RULES

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BUREAU OF PROFESSIONAL LICENSING

PUBLIC HEALTH CODE—GENERAL RULES

Filed with the secretary of state on May 16, 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 by sections 16145, 16194, 16201, and 16221 of the public health code, 1978 PA 368, MCL 333.16145, 333.16194, 333.16201, and 333.16221, 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 338.7001a, R 338.7002, R 338.7002b, and R 338.7004 of the Michigan Administrative Code are amended, as follows:

R 338.7001a Biennial license and registration renewal; expiration.

Rule 1a. (1) The following licenses and registrations expire biennially and must be renewed every 2 years on or before the date indicated:

Acupuncture	Issue date
Audiology	Issue date
Chiropractic	Issue date
Dental Therapy	Issue date
Nursing	Issue date
Nursing home administrators	Issue date
Occupational therapy	Issue date
Optometry	Issue date
Pharmacy	Issue date
Psychology	Issue date
Speech-language pathology	Issue date

(2) A license or registration having a limitation may be renewed for a term less than 2 years.

R 338.7002 Triennial license or registration renewal; expiration.

Rule 2. (1) The following licenses and registrations expire triennially and must be renewed every 3 years on or before the date indicated:

Athletic trainer	Issue date
Counseling	Issue date
Dentistry	Issue date
Dental Assistant	Issue date

Dental Hygienist	Issue date
Genetic Counseling	Issue date
Massage therapy	Issue date
Medicine	Issue date
Osteopathic medicine and surgery	Issue date
Podiatric medicine and surgery	Issue date
Social work	Issue date
Veterinary medicine	Issue date

(2) The following licenses issued or renewed on or after the effective date of these rules expire triennially and must be renewed every 3 years on or before the date indicated:

Marriage and family therapy	Issue date
Physician's assistants	Issue date
Respiratory care	Issue date

(3) The following licenses issued or renewed on or after the effective date of these rules and on or after the effective date of the applicable profession’s next rules revision expire triennially and must be renewed every 3 years on or before the date indicated:

Midwifery	Issue date
Physical Therapy	Issue date
Sanitarians	Issue date

(4) A license or registration having a limitation may be renewed for a term less than 3 years.

R 338.7002b Minimum English language standard.

Rule 2b. (1) Under section 16174(1)(d) of the code, MCL 333.16174, an applicant seeking licensure, registration, relicensure, if lapsed for more than 3 years, or reregistration, if lapsed for more than 3 years, shall demonstrate a working knowledge of the English language under the minimum standards established by the department.

(2) To demonstrate a working knowledge of the English language, the applicant shall establish that the applicant meets 1 of the following:

(a) The applicant’s health professional educational program was taught in English.

(b) The applicant supplies transcripts establishing that the applicant earned not less than 60 college level credits from an English-speaking undergraduate or graduate school.

(c) The applicant’s credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state by a board-approved credentialing agency.

(d) The applicant obtained an overall score of not less than 176 overall and 185 speaking on the Cambridge English (B2 First, C1 Advanced, or C2 Proficiency) Examination.

(e) The applicant obtained a passing score of 650 or higher on the Examination for the Certificate of Competency in English (ECCE) test developed by Michigan Language Assessment, as demonstrated by a certificate of competency or certificate of competency with honors.

(f) The applicant obtained a passing score of 650 or higher on the Examination for the Certificate of Proficiency in English (ECPE) test developed by Michigan Language Assessment, as demonstrated by a certificate of proficiency or certificate of proficiency with honors.

(g) The applicant obtained a total score of not less than 6.5 on the International English Language Testing System (IELTS) Academic test within 2 years of the date of application.

(h) The applicant obtained an overall score of not less than 55 on the 4-skill Michigan English Test (MET) developed by Michigan Language Assessment.

(i) The applicant obtained an overall score of not less than 300 on the Occupational English Test (OET).

(j) The applicant obtained an overall score of not less than 55 and not less than 50 on any section of the Pearson PTE Academic Examination.

(k) The applicant obtained a total score of not less than 80 on the Test of English as a Foreign Language Internet-Based Test (TOEFL-IBT) administered by the Educational Testing Service within 2 years of the date of application.

(l) The applicant obtained a score of not less than 725 on the reading and listening section, not less than 150 on the writing section, and not less than 160 on the speaking section of the Test of English for International Communication (TOEIC) within 2 years of the date of application.

R 338.7004 Implicit bias training standards.

Rule 4. (1) An individual applying for licensure or registration under article 15 of the code, MCL 333.16101 to 333.18838, except those seeking to be licensed under part 188 of the code, MCL 333.18801 to 333.18838, shall have completed a minimum of 2 hours of implicit bias training within the 5 years immediately preceding issuance of the license or registration.

(2) An individual applying for licensure or registration renewal, reregistration, or relicensure under article 15 of the code, MCL 333.16101 to 333.18838, except those licensed under part 188 of the code, MCL 333.18801 to 333.18838, shall have completed a minimum of 1 hour of implicit bias training for each year of the applicant's license or registration cycle. Unless prohibited by the code or rules, this training may be used to satisfy other training or continuing education requirements for license renewal.

(3) A licensee or registrant shall not carry forward implicit bias training hours earned during 1 renewal cycle to the next renewal cycle.

(4) A licensee or registrant shall not earn implicit bias training hours for completing implicit bias training that is identical or substantially identical to implicit bias training that the licensee or registrant has already completed during the same renewal cycle.

(5) The implicit bias training must be related to reducing barriers and disparities in access to and delivery of healthcare services and meet all of the following requirements:

(a) Training content must include, but is not limited to, 1 or more of the following topics:

(i) Information on implicit bias, equitable access to healthcare, serving a diverse population, diversity and inclusion initiatives, and cultural sensitivity.

(ii) Strategies to remedy the negative impact of implicit bias by recognizing and understanding how it impacts perception, judgment, and actions that may result in inequitable decision making, failure to effectively communicate, and result in barriers and disparities in the access to and delivery of healthcare services.

(iii) The historical basis and present consequences of implicit biases based on an individual's characteristics.

(iv) Discussion of current research on implicit bias in the access to and delivery of healthcare services.

(b) Training must include strategies to reduce disparities in access to and delivery of healthcare services and the administration of pre- and post-test implicit bias assessments.

(c) Acceptable sponsors of this 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 was approved by any board created under article 15 of the code, MCL 333.16101 to 333.18838, except under part 188 of the code, MCL 333.18801 to 333.18838, for initial licensure or registration or for the accumulation of continuing education credits.

(iv) Training offered by an accredited college or university.

(v) Training offered by an organization specializing in diversity, equity, and inclusion issues.

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

(i) A teleconference or webinar that allows live synchronous interaction that provides for the opportunity for participants to interact with the instructor and other participants.

(ii) A live presentation that provides for the opportunity for participants to interact with the instructor and other participants.

(iii) An asynchronous teleconference or webinar.

(6) Submission of an application for licensure, registration, or renewal constitutes an applicant's certificate of compliance with the requirements of this rule. The licensee or registrant shall retain documentation of meeting the requirements of this rule for a period of 6 years after the date of applying for licensure, registration, or renewal. The department may select and audit a sample of licensees or registrants and request documentation of proof of compliance with this rule. If audited by the department, the licensee or registrant shall provide the proof of completion of training, including either of the following:

(a) A completion certificate issued by the training program that includes the date of the training, the program sponsor's name, the title of the program, and licensee's or registrant's name.

(b) A self-attestation by the licensee or registrant that includes the date of the training, the program sponsor's name, the title of the program, and licensee's or registrant's name.

CERTIFICATE OF NEED REVIEW STANDARDS

MCL 24.208 states in part:

Sec. 8. The Office of Regulatory Reform shall publish the Michigan register at least once each month. The Michigan register shall contain all of the following:

* * *

(k) All of the items in section 7(l) after final approval by the certificate of need commission or the statewide health coordinating council under section 22215 or 22217 of the public health code, 1978 PA 368, MCL 333.22215 and 333.2217.

MCL 24.207 states in part:

Sec. 7. "Rule" means an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency. Rule does not include any of the following:

* * *

(l) All of the following, after final approval by the certificate of need commission or the statewide health coordinating council under section 22215 or 22217 of the public health code, 1978 PA 368, MCL 333.22215 and 333.22217:
(i) The designation, deletion, or revision of covered medical equipment and covered clinical services.
(ii) Certificate of need review standards
(iii) Data reporting requirements and criteria for determining health facility viability.
(iv) Standards used by the department of community health in designating a regional certificate of need review agency.
(v) The modification of the 100 licensed bed limitation for short-term nursing care programs set forth in section 22210 of the public health code, 1978 PA 368, MCL 333.22210.

CERTIFICATE OF NEED REVIEW STANDARDS

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
SYNOPSIS FOR PUBLICATION IN THE MICHIGAN REGISTER
PURSUANT TO THE ADMINISTRATIVE PROCEDURES ACT, 1969 PA 306, MCL 24.208(1)(k)

HOSPITAL BEDS
Final Approval by the CON Commission 3/14/24 and Effective 5/6/24

The language changes include the following:

1. Section 2(1): Updated definitions for “Alcohol and substance abuse hospital” and Obstetrics patient days of care” to reflect updated MSDRGs:

   (c) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by MSDRGs –894 - 897. THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.

   (gg) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant’s Michigan Inpatient Data Base data ages 15 AND OVER with MSDRGs LISTED IN APPENDIX E (obstetrical discharges). THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.

2. Modified Section 6: Added language allowing continued operation for an LTAC or IRF hospital after closure of host hospital:

   Section 6. Requirements for approval -- new beds in a hospital, LTAC HOSPITAL OR IRF HOSPITAL OR SUBSTANCE ABUSE HOSPITAL; RELICENSURE OF BEDS BY A HOST HOSPITAL; LTAC OR IRF HOSPITAL SPACE RENEWAL OF LEASE; AND LTAC OR IRF HOSPITAL CONTINUED OPERATION AFTER HOST HOSPITAL CLOSES

(2) An applicant proposing to begin operation as a new LTAC hospital, IRF hospital, or alcohol and substance abuse hospital within an existing licensed, host hospital, OR AN LTAC OR IRF HOSPITAL CONTINUING OPERATION AFTER A HOST HOSPITAL CLOSES, shall demonstrate that it meets all of the requirements of this subsection:

(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements, UPON VOLUNTARY CLOSURE OF THE HOST HOSPITAL, or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

(D) VOLUNTARY CLOSURE OF THE HOST HOSPITAL. AN LTAC or IRF HOSPITAL PROPOSING TO CONTINUE OPERATION AFTER ITS HOST HOSPITAL VOLUNTARILY CLOSES SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW AND SHALL BE PROCESSED UNDER THE SAME PROCEDURES FOR NON-SUBSTANTIVE REVIEW. THE APPLICANT SHALL ALSO DEMONSTRATE IT MEETS ALL OF THE FOLLOWING:

(1) THE LTAC OR IRF HOSPITAL HAS OR AGREES TO PERMANENTLY ACQUIRE ITS LTAC OR IRF HOSPITAL BEDS FROM THE HOST HOSPITAL AS DEMONSTRATED BY A CURRENT AGREEMENT WITH THE HOST HOSPITAL OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,

(2) THE LTAC OR IRF HOSPITAL HAS OR AGREES THAT IT WILL HAVE CONTINUED CONTROL OF ITS PHYSICAL SPACE AS DEMONSTRATED BY A CURRENT EXECUTED LEASE, PROOF OF OWNERSHIP, AN AGREEMENT TO LEASE OR PURCHASE OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,

(3) THE LTAC OR IRF AGREES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS, AND

(4) THE LTAC OR IRF HOSPITAL APPROVED UNDER THIS SUBSECTION AGREES THAT IF IT CEASES OPERATION AS AN LTAC OR IRF HOSPITAL IT WILL DISPOSE OF ITS LICENSED BEDS BY EITHER (i) RELOCATING THE BEDS TO AN EXISTING, LICENSED HOSPITAL OR (ii) DELICENSING THE BEDS.

3. Section 9: Added project delivery requirements for freestanding LTAC or IRF hospital after closure of host hospital:

(6) AN LTAC or IRF HOSPITAL APPROVED PURSUANT TO SECTION 6(2) MAY CONTINUE TO OPERATE AFTER ITS HOST HOSPITAL CLOSES AND SHALL BE IN COMPLIANCE WITH ALL OF THE FOLLOWING:

(a) BE SEPARATELY LICENSED,

(b) MAINTAIN ITS OWN GOVERNING BODY,

(c) OWN AND OPERATE ITS APPROVED BEDS, AND

(d) OPERATIONS MUST CONTINUE WITHOUT INTERRUPTION INCLUDING MAINTAINING ITS OWN STAFF, SUPPLIES, AND SERVICES.

4. Added APPENDIX E to house Obstetrics MSDRGs which will be updated as MIDB data becomes available.

5. Section 9(4): Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:

   (f) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

Complete Standards

A complete set of the approved language can be found at https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Doing-Business-with-MDHHS/Health-Care-Providers/Certificate-of-Need/CON-Review-Standards/HB_Standards.pdf?rev=9a413d776a78434e8660939e989abbc6&hash=DB0A3040C8836DDD30D1BBB92624C608

A hard copy may be obtained, for a fee, by sending a written request to:

Michigan Department of Health and Human Services
Policy, Planning and Operational Support Administration
Office of Policy and Planning
P.O. Box 30195
Lansing, MI 48909
(517) 420-1273
Email address: MDHHS-ConWebTeam@michigan.gov

CERTIFICATE OF NEED REVIEW STANDARDS

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
SYNOPSIS FOR PUBLICATION IN THE MICHIGAN REGISTER
PURSUANT TO THE ADMINISTRATIVE PROCEDURES ACT, 1969 PA 306, MCL 24.208(1)(k)

OPEN HEART SURGERY (OHS) SERVICES
Final Approval by the CON Commission 3/14/24 and Effective 5/6/24

The language changes include the following:

1. Section 8(4)(d): Revised monitoring and reporting requirements for STS star ratings:

   (d) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within OHS programs. The Department shall use ALL COMPOSITES IN the STS Composite Star Rating System, INCLUDING BUT NOT LIMITED TO: which currently includes coronary artery bypass graft composite (CABG), aortic valve replacement (AVR), AND THE MULTIPROCEDURAL composite MEASURE., and plans to add additional cardiac surgical composites each year. The Department or its designee shall require that the applicant hospital submit a summary report as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. The outcomes database must undergo statewide auditing.

2. Section 8(4): Revised reporting procedure for STS Composite Star Ratings:

   (e) The applicant hospital shall utilize and report the STS Composite Star Rating System for all procedures as follows:

   (i) IF THE PROGRAM DOES NOT QUALIFY TO RECEIVE A STAR RATING IN ONE OR MORE COMPOSITE METRICS BUT RECEIVES A TWO-STAR OR HIGHER RATING IN AT LEAST ONE COMPOSITE METRIC FOR THE SAME TIME PERIOD, THE PROGRAM SHALL BE CONSIDERED IN COMPLIANCE.

   (ii) If the program receives a one-star rating in any composite metric, they shall submit a report to the Department explaining the reason(s) for the unsatisfactory rating.

   (iii) If the program receives two one-star ratings in a row in the same composite metric, they shall submit an action plan to the Department detailing specific actions to rectify the program deficiencies.

(iv) If the program receives two one-star ratings within the same composite metric, the program may have two years to obtain a minimum two-star rating within that composite metric. Upon receipt of a two-star or higher rating, the program SHALL be considered in compliance.

(f) IF THE PROGRAM PARTICIPATES IN THE STS COMPOSITE STAR RATING SYSTEM AND DOES NOT RECEIVE A STAR RATING FOR ANY REASON, THEY SHALL SUBMIT A REPORT TO THE DEPARTMENT EXPLAINING THE REASON(S) FOR NOT RECEIVING A STAR RATING.

3. Section 8(4): Added subsection to require a notification to the Department at least 30 days prior to a planned decrease or discontinuation of services:

(h) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

Complete Standards

A complete set of the approved language can be found at https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Doing-Business-with-MDHHS/Health-Care-Providers/Certificate-of-Need/CON-Review-Standards/OHS_Standards.pdf?rev=fe8d310135764df98287d1940c165e9c&hash=800A20AC8C6AEC74B3611CE16885FCDF

A hard copy may be obtained, for a fee, by sending a written request to:

Michigan Department of Health and Human Services
Policy, Planning and Operational Support Administration
Office of Policy and Planning
P.O. Box 30195
Lansing, MI 48909
(517) 420-1273
Email address: MDHHS-ConWebTeam@michigan.gov

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ADMINISTRATIVE RULES
ENROLLED SENATE AND HOUSE BILLS
SIGNED INTO LAW OR VETOED
(2024 SESSION)

Mich. Const. Art. IV, §33 provides: "Every bill passed by the legislature shall be presented to the governor before it becomes law, and the governor shall have 14 days measured in hours and minutes from the time of presentation in which to consider it. If he approves, he shall within that time sign and file it with the secretary of state and it shall become law . . . If he does not approve, and the legislature has within that time finally adjourned the session at which the bill was passed, it shall not become law. If he disapproves . . . he shall return it within such 14-day period with his objections, to the house in which it originated."

Mich. Const. Art. IV, §27, further provides: "No act shall take effect until the expiration of 90 days from the end of the session at which it was passed, but the legislature may give immediate effect to acts by a two-thirds vote of the members elected to and serving in each house."

MCL 24.208 states in part:

"Sec. 8. (1) The Office of Regulatory Reform shall publish the Michigan register at least once each month. The Michigan register shall contain all of the following:

* * *

(b) On a cumulative basis, the numbers and subject matter of the enrolled senate and house bills signed into law by the governor during the calendar year and the corresponding public act numbers.

(c) On a cumulative basis, the numbers and subject matter of the enrolled senate and house bills vetoed by the governor during the calendar year."

2024 Michigan Public Acts Table

Legislative Service Bureau
Legal Division, Statutory Compiling and Law Publications Unit
124 W. Allegan, Lansing, MI 48909

June 11, 2024
Compiled through PA 57 of 2024

PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0001	4416		Yes	2/21/2024	2/21/2024	2/21/2024	***Probate**; other*, general amendments to the estates and protected individuals code; provide for. ***(Rep. Graham Filler)***
0002	4417		Yes	2/21/2024	2/21/2024	5/21/2024	***Vehicles**; title*, transfer of ownership of vehicle to surviving spouse or heir after owner's death; modify maximum value and adjust for cost of living. ***(Rep. Graham Filler)***
0003	4418		Yes	2/21/2024	2/21/2024	2/21/2024	***Probate**; other*, uniform transfers to minors act; modify amount of transfer allowed. ***(Rep. Kelly Breen)***
0004	4419		Yes	2/21/2024	2/21/2024	5/21/2024	***Watercraft**; other*, watercraft eligible for issuance of certificate of title transferring deceased owner's interest; increase maximum value of, subject to Consumer Price Index. ***(Rep. Kelly Breen)***
0005	4845		Yes	2/21/2024	2/21/2024	2/21/2024	***Highways**; memorial*, portion of M-125; designate as the "Captain Joseph M. Liedel Memorial Highway". ***(Rep. William Bruck)***
0006	4325		No	2/21/2024	2/21/2024	**	***Environmental protection**; other*, criminal penalties and civil fines for unlawful dumping of garbage; provide for. ***(Rep. Helena Scott)***
0007	4824		No	2/27/2024	2/27/2024	** #	***Administrative procedure**; other*, cross-reference to administrative procedures act within the natural resources and environmental protection act; update. ***(Rep. Donavan McKinney)***
0008	4825		No	2/27/2024	2/27/2024	** #	***Administrative procedure**; other*, cross-reference to administrative procedures act within the state police retirement act of 1986; update. ***(Rep. Jenn Hill)***

* - I.E. means Legislature voted to give the Act immediate effect.
** - Act takes effect on the 91st day after sine die adjournment of the Legislature.
*** - See Act for applicable effective date.
\+ - Line item veto.
++ - Pocket veto.
\# - Tie bar.

PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0009	4826		No	2/27/2024	2/27/2024	**	***Environmental protection***; *other*; environmental rules review committee; eliminate. ***(Rep. Sharon MacDonell)***
0010	4677		No	2/27/2024	2/27/2024	**	***Children***; *foster care*; assessments of education facilities at child care institutions; require. ***(Rep. Stephanie A. Young)***
0011	4678		No	2/27/2024	2/27/2024	**	***Children***; *child care*; assessments of education facilities at child care institutions; require. ***(Rep. Kimberly Edwards)***
0012	4979		Yes	3/12/2024	3/12/2024	3/12/2024	***Property tax***; *assessments*; procedures related to appointing designated assessors; modify. ***(Rep. Jenn Hill)***
0013	4857		No	3/12/2024	3/12/2024	**	***Agriculture***; *plants*; classification of milkweed as a noxious or exotic weed by local governments; prohibit. ***(Rep. Samantha Steckloff)***
0014	4524		Yes	3/12/2024	3/12/2024	6/10/2024	***Courts***; *drug court*; termination procedure for drug treatment courts; modify. ***(Rep. Joey Andrews)***
0015	4522		Yes	3/12/2024	3/12/2024	3/12/2024	***Courts***; *other*; family treatment court; create. ***(Rep. Kelly Breen)***
0016	4190		No	3/12/2024	3/12/2024	**	***Construction***; *asbestos*; public contracts for asbestos abatement projects; require disclosure of environmental violations. ***(Rep. Curtis VanderWall)***
0017	4185		No	3/12/2024	3/12/2024	**	***Labor***; *health and safety*; provisions related to civil penalties; modify with respect to repeated violations and asbestos-related violations. ***(Rep. Denise Mentzer)***
0018		0057	Yes	3/12/2024	3/12/2024	6/10/2024 #	***Controlled substances***; *drug paraphernalia*; sale of nitrous oxide devices; prohibit. ***(Sen. Stephanie Chang)***

* - I.E. means Legislature voted to give the Act immediate effect.
** - Act takes effect on the 91st day after sine die adjournment of the Legislature.
*** - See Act for applicable effective date.
+ - Line item veto.
++ - Pocket veto.
# - Tie bar.

PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0019		0058	Yes	3/12/2024	3/12/2024	6/10/2024 #	***Controlled substances***; *drug paraphernalia*; penalties for sale of nitrous oxide devices; provide for. ***(Sen. Joseph Bellino)***
0020		0721	Yes	3/28/2024	3/28/2024	3/28/2024	***Property***; *recording*; marketable record title; modify. ***(Sen. Jeremy Moss)***
0021	4511		No	3/28/2024	3/28/2024	** #	***Vehicles***; *equipment*; child restraint safety seats; require positioning of car seats to depend on weight of child, and make other revisions. ***(Rep. Carrie Rheingans)***
0022	4512		No	3/28/2024	3/28/2024	** #	***Vehicles***; *equipment*; waiver of civil fine and costs for a violation of section 710d; revise requirements. ***(Rep. John Fitzgerald)***
0023	4676		No	3/28/2024	3/28/2024	**	***Children***; *foster care*; education requirements for children placed in foster care; provide for. ***(Rep. Stephanie A. Young)***
0024	5207		No	4/1/2024	4/1/2024	** #	***Family law***; *other*; surrogate parenting act; repeal, and establish the assisted reproduction and surrogacy parentage act. ***(Rep. Samantha Steckloff)***
0025	5208		No	4/1/2024	4/1/2024	** #	***Records***; *birth*; birth certificates issued for a child whose parentage is determined under the assisted reproduction and surrogacy parentage act; provide for. ***(Rep. Christine Morse)***
0026	5209		No	4/1/2024	4/1/2024	** #	***Criminal procedure***; *sentencing guidelines*; sentencing guidelines for surrogate parentage contracts involving minors or intellectually disabled and for compensation; remove. ***(Rep. Kelly Breen)***
0027	5210		No	4/1/2024	4/1/2024	** #	***Probate***; *wills and estates*; intestate succession; revise for children conceived by assisted reproduction or surrogacy. ***(Rep. Jason Hoskins)***
0028	5211		No	4/1/2024	4/1/2024	**	***Family law***; *paternity*; determination under the paternity act; exclude children conceived by assisted reproduction or surrogacy. ***(Rep. Jennifer Conlin)***

* - I.E. means Legislature voted to give the Act immediate effect.
** - Act takes effect on the 91st day after sine die adjournment of the Legislature.
*** - See Act for applicable effective date.
\+ - Line item veto.
++ - Pocket veto.
\# - Tie bar.

PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0029	5212		No	4/1/2024	4/1/2024	** #	***Family law***; *other*; reference to surrogate parenting act; eliminate, and refer to the assisted reproduction and surrogacy parentage act. ***(Rep. Jason Morgan)***
0030	5213		No	4/1/2024	4/1/2024	** #	***Family law***; *paternity*; determination under the summary support and paternity act; exclude children conceived by assisted reproduction or surrogacy. ***(Rep. Penelope Tsernoglou)***
0031	5214		No	4/1/2024	4/1/2024	** #	***Family law***; *paternity*; determination under the acknowledgment of parentage act; exclude children conceived by assisted reproduction or surrogacy. ***(Rep. Laurie Pohutsky)***
0032	5215		No	4/1/2024	4/1/2024	** #	***Family law***; *paternity*; determination under the genetic parentage act; exclude children conceived by assisted reproduction or surrogacy. ***(Rep. Amos O'Neal)***
0033	4012		Yes	4/2/2024	4/2/2024	4/2/2024	***Traffic control***; *speed restrictions*; procedure for establishing speed limits; modify. ***(Rep. Bradley Slagh)***
0034	4183		Yes	4/2/2024	4/2/2024	4/2/2024	***Vehicles***; *historic*; historic vehicle plates allowed driving time; expand. ***(Rep. John R. Roth)***
0035	5048		Yes	4/2/2024	4/2/2024	4/2/2024	***Taxation***; *hotel-motel*; local units to levy a hotel tax; allow and increase rate allowed to be levied by counties. ***(Rep. John Fitzgerald)***
0036	5527		No	4/27/2024	4/29/2024	**	***Education***; *safety*; cardiac emergency response plans; modify. ***(Rep. John Fitzgerald)***
0037	5528		No	4/27/2024	4/29/2024	**	***Education***; *athletics*; CPR and AED certification requirements for athletic coaches; provide for. ***(Rep. Tyrone Carter)***
0038	5392		Yes	4/30/2024	4/30/2024	4/30/2024	***Criminal procedure***; *sentencing*; sunset on certain costs that may be imposed upon criminal conviction; modify. ***(Rep. Sarah Lightner)***

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+ - Line item veto.
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# - Tie bar.

PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0039	4608		No	4/30/2024	4/30/2024	**	***Health occupations***; *dietitians and nutritionists*; licensure of dietitian nutritionists; provide for. ***(Rep. Laurie Pohutsky)***
0040	5096		Yes	5/17/2024	5/17/2024	5/17/2024	***Economic development***; *renaissance zones*; designation of renaissance zone; modify. ***(Rep. Kristian Grant)***
0041		0027	No	5/21/2024	5/21/2024	**	***Insurance***; *health insurers*; equitable coverage for behavioral health and substance use disorder treatment; provide for. ***(Sen. Sarah Anthony)***
0042	5103		No	5/22/2024	5/22/2024	**	***Traffic control***; *driver license*; certain requirements for obtaining a driver license; remove. ***(Rep. Donavan McKinney)***
0043	4596		No	5/22/2024	5/22/2024	**	***Environmental protection***; *sewage*; labeling standards for disposable wipes products; provide for. ***(Rep. Denise Mentzer)***
0044	4523		Yes	5/22/2024	5/22/2024	8/20/2024	***Courts***; *other*; violent offender eligibility for mental health court; modify. ***(Rep. Kara Hope)***
0045	4525		Yes	5/22/2024	5/22/2024	8/20/2024	***Courts***; *drug court*; violent offender eligibility for drug treatment court; modify. ***(Rep. Graham Filler)***
0046	4343		No	5/22/2024	5/22/2024	**	***Financial institutions***; *payday lending*; legislative report requirement concerning deferred presentment service providers and transactions; revise. ***(Rep. Jennifer Conlin)***
0047	5534		No	5/22/2024	5/22/2024	**	***Criminal procedure***; *sentencing*; supreme court to determine court operation costs and propose new funding system; require. ***(Rep. Kelly Breen)***
0048		0249	No	5/22/2024	5/22/2024	**	***Health occupations***; *emergency medical services personnel*; examinations for certain emergency medical services personnel; modify, and require certain notices from education program sponsors. ***(Sen. Kevin Hertel)***

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	HB	SB					
0049		0518	Yes	6/6/2024	6/6/2024	6/6/2024	***Education**; teachers and administrators*; interim teaching certification process; modify. ***(Sen. Darrin Camilleri)***
0050		0227	Yes	6/6/2024	6/6/2024	6/6/2024	***Children**; child care*; emergency safety intervention in a children's therapeutic group home; modify conditions for. ***(Sen. Dan Lauwers)***
0051	4579		No	6/6/2024	6/6/2024	**	***Insurance**; health insurers*; reimbursement rate for telehealth visits; require to be the same as reimbursements for office visits. ***(Rep. Natalie Price)***
0052	4131		No	6/6/2024	6/6/2024	**	***Insurance**; health insurers*; coverage for health care services provided through telemedicine; modify. ***(Rep. Tullio Liberati)***
0053	4580		No	6/6/2024	6/6/2024	**	***Human services**; medical services*; reimbursement rate for telehealth visits; require to be the same as reimbursements for office visits. ***(Rep. Felicia Brabec)***
0054	4213		No	6/6/2024	6/6/2024	**	***Mental health**; code*; definition of distant site for a telemedicine visit; provide for. ***(Rep. Christine Morse)***
0055	4186		No	6/6/2024	6/6/2024	**	***Construction**; asbestos*; provision allowing the withholding of payment to asbestos abatement contractors or demolition contractors for environmental violations; require certain local government contracts to contain, and require certain disclosures by asbestos abatement contractors and demolition contractors. ***(Rep. Donavan McKinney)***
0056	4188		No	6/6/2024	6/6/2024	**	***Environmental protection**; air pollution*; asbestos emissions program; impose fee on notification of demolition or renovation and specify minimum rates of inspection. ***(Rep. Abraham Aiyash)***
0057	4101		No	6/6/2024	6/6/2024	**	***Health occupations**; speech-language pathologists*; temporary licensing of speech-language pathologists; modify. ***(Rep. Curtis VanderWall)***

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