MICHIGAN BOARD OF PHARMACY
DECEMBER 20, 2023, MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on December 20, 2023, at 611 West Ottawa Street, Upper-Level Conference Room 3, Lansing, Michigan 48933.

CALL TO ORDER

Grace Sesi, PharmD, Chairperson, called the meeting to order at 10:00 a.m.

ROLL CALL

Members Present: Grace Sesi, PharmD, Chairperson
Michael Sleiman, PharmD, Vice Chairperson
Keith Binion, BS, C.Ph.T.
Pierre Boutros, R.Ph.
Scott Ciarkowski, PharmD, MBA
Rony Foumia, R.Ph.
Kyle McCree, Public Member
Kelli Oldham, Public Member
Sandra Taylor, R.Ph.

Members Absent: None

Staff Present: Jon Campbell, Director, Investigations & Inspections Division
Marshall Hooks, Senior Analyst, Compliance Section
Jennifer Shaltry, JD, Departmental Specialist,
Boards and Committees Section
Michele Wagner-Gutkowski, JD, Assistant Attorney General
Inna Volkova, JD, Director, Enforcement Division
Stephanie Wysack, Board Support Technician
Boards and Committees Section

APPROVAL OF AGENDA

MOTION by Boutros, seconded by Sleiman, to approve the amended agenda, with the addition of new item 5. Department Presentation.

A voice vote followed.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Oldham, seconded by Binion, to approve the October 18, 2023, meeting minutes as written.

A voice vote followed.

MOTION PREVAILED

Department Presentation

Campbell and Volkova provided statistics on authorized investigations for FY23.

Discussion was held.

REGULATORY CONSIDERATONS

Petition for Reinstatement

Kamika Patricia-Mae Ashburn, Ph.T.

MOTION by Ciarkowski, seconded by Binion, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Boutros, seconded by Ciarkowski, to grant reinstatement of the pharmacy technician license. Petitioner is placed on probation with no violations of the Michigan Public Health Code.

Discussion was held.

A roll call vote was taken: Yeas: Binion, Boutros, Ciarkowski, Foumia, McCree, Taylor, Sleiman, Sesi
Nays: Oldham

MOTION PREVAILED

Proposal for Decision – Reinstatement

Anthony O. Akande, R.Ph.

MOTION by Foumia, seconded by Ciarkowski, to accept the Proposal for Decision and deny the petition for reinstatement.

A roll call vote was taken: Yeas: Binion, Boutros, Ciarkowski, Foumia, McCree, Oldham, Taylor, Sleiman, Sesi
Nays: None

MOTION PREVAILED

OLD BUSINESS

None

NEW BUSINESS

Amended 2024 Public Notice

Sesi stated that the date of the meeting for April 2024 had changed from the 17th to the 23rd.

Continuing Education

Foumia stated that there were no programs submitted since the last meeting in October.

Pharmacy Technician Programs and/or Examinations

Valiant Compounding Pharmacy

Binion stated that the pharmacy technician committee recommended approval of the pharmacy technician program and examination.

MOTION by Boutros, seconded by Foumia, to accept the recommendation of the committee and approve the pharmacy technician training program and examination.

A roll call vote was taken: Yeas: Binion, Boutros, Ciarkowski, Foumia, McCree, Oldham, Taylor, Sleiman, Sesi
Nays: None

MOTION PREVAILED

Walgreens

Binion stated that the pharmacy technician committee recommended approval of the pharmacy technician program and examination.

MOTION by Foumia, seconded by McCree, to accept the recommendation of the committee and approve the pharmacy technician training program and examination.

A roll call vote was taken: Yeas: Binion, Boutros, Ciarkowski, Foumia, McCree, Taylor, Sesi
Nays: None
Recuse: Oldham, Sleiman

MOTION PREVAILED

Waiver of 10-Mile Limitation on Remote Pharmacy

Peninsula Pharmacy

MOTION by Foumia, seconded by Ciarkowski, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Foumia, seconded by Boutros, to approve the request for a Waiver of the 10-Mile Limitation on a Remote Pharmacy.

A roll call vote was taken: Yeas: Binion, Boutros, Ciarkowski, Foumia, McCree, Oldham, Taylor, Sleiman, Sesi
Nays: None

MOTION PREVAILED

Rules Discussion

Pharmacy – Controlled Substance – Public Comments

Shaltry provided an overview of the public comment summary (attached) and the rules committee's recommendations.

Discussion was held.

MOTION by Foumia, seconded by Boutros, to accept the rules committee's recommendations to public comments, as presented.

A roll call vote was taken: Yeas: Binion, Boutros, Foumia, McCree, Oldham, Taylor, Sleiman, Sesi
Nays: Ciarkowski

MOTION PREVAILED

Chair Report

Binion stated that he attended the NABP Member Forum Meeting in Rosemont, Illinois, from November 29 – 30, 2023. At the meeting they discussed staff shortages across the nation and possible solutions for retention as well as artificial intelligence moving into pharmacies and measures that could be taken to assist with safety measures.

Sesi stated that pharmacies do not work the same as fast-food chains in that you can "have it your way." The general public should keep this in mind and respect the stressful environment that the pharmacy staff is in.

Ciarkowski and Taylor complimented pharmacy technicians for adapting to the recent changes in USP sanitation standards.

Sesi stated that the 120th NABP Annual meeting will be held from May 14 – 17, 2024 in Fort Worth, Texas. The 2024 91st Annual District IV meeting will be held from September 18 – 20, 2024, in Detroit, Michigan. She encouraged board members to attend.

Sesi read a release sent by Governor Whitmer to the Michigan Department of Licensing and Regulatory Affairs. Sesi stated that the board was on track with the Governor's request to remove barriers to licensure, such as removing the MPJE examination.

Department Update

Shaltry stated that the bureau will hold the next board member training on February 20, 2024, via Zoom. All board members are welcome to attend.

Shaltry explained the steps of the rule's promulgation process.

Wysack reminded board members to check their state email on a regular basis as this is the form of communication with the department.

PUBLIC COMMENT

Chris Norello asked the board to clarify in the rules the difference between "training" and "continuing education."

Nichole Cover, R.Ph., thanked the board for their work on the controlled substance rules. She asked that the board continue to work on uniting the profession and consider how the rules could be written to encourage change in the profession, instead of keeping it in the past.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held February 14, 2024, at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper-Level Conference Center Room 3, Lansing, Michigan 48933.

ADJOURNMENT

MOTION by Boutros, seconded by McCree, to adjourn the meeting at 11:29 a.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on: February 14, 2024

Prepared by:
Stephanie Wysack, Board Support Technician December 21, 2023
Bureau of Professional Licensing

Pharmacy - Controlled Substances – MOAHR #2022-06 LR
Public Comment Summary

Testimony/Comments Received:

Baran, Rose, Pharm D
Chludzinski, Paul, RPh, Pharmacy Regulatory Specialist, Henry Ford Hospital
O'Connor, Martha

Rule 338.3102 Definitions I to P.

Section Numbers	Commenter	Comment
Subrule d	Baran	ASAP 4.1 Standard is outdated. The current Standard is 4.2B. The 2023 version 5.0 to be implemented January 2024. **Suggested Change:** 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."
Subrule f	Baran	The definition in the Code of Federal Regulations 21 USC 207.33(a) does not have vendor. "The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type." Suggested Change: Delete vendor in the definition.
Subrule (h)(iv)	Baran	Residents of a tribal nation may only have a tribal government issued identification. To make it clear that a tribal government issued identification can be used for MAPS. **Suggested Change:** Add (D) to 338.3102(**h**)(iv)(D) A tribal government identification number obtained from a tribal government issued identification.
Rules Committee Response	Subrule d: The committee agreed with the suggested changes. Subrule f: The committee agreed with the suggested changes.	

	Subrule (h)(iv) The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.

R 338.3102 Definitions; I to P.

Rule 2. As used in these rules:

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

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

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

(~~c~~**d**) "~~Michigan automated prescription system (~~MAPS~~)~~ claim form" means a form, ~~to be~~ determined by the department~~,~~ that is in the format and includes the information as specified by the ~~American Society for Automation in Pharmacy (~~ASAP~~)~~ ~~4.1~~ **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.

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

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

(~~f~~**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) ~~Any 1~~**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.

~~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.~~

(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.

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

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

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

Board Response	

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

Section Numbers	Commenter	Comment
Removal of Gabapentin from the schedule	Chludzinski	Regarding the proposal to remove gabapentin as a Schedule 5 drug (R338.3111) to align with the federal scheduling and the majority of the states in the Great Lakes Region: If the Public Health Code requires the board to schedule a substance if it has a potential for abuse (333.7203), and gabapentin presents a potential for abuse, shouldn't it remain a scheduled drug in Michigan? • *Gabapentin Presents High Potential for Misuse* (November 2022). https://www.pharmacytimes.com/view/gabapentin-presents-high-potential-for-misuse • *Gabapentin Abuse Potential* (June 2023), https://americanaddictioncenters.org/neurontin-abuse
3(d)	O'Connor	Subrule (3)(d) pertains to the definition of isomers. It needs clarification to avoid confusion with the chart. **Suggested language:** **(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~~, which includes the optical, position, and geometric isomers~~.
Rules Committee Response	The committee stated that Michigan is in the minority with scheduling this drug. It was scheduled to reduce prescribing amounts and that has not changed with the scheduling. This drug is widely used, and the scheduling creates difficulty for the prescribers, the pharmacists, and the patients in receiving the drug. The committee wanted to continue forward with the removal of this drug from scheduling. Subrule 3(d): The committee agreed with the suggested change. Rule edits per the committee’s suggestion are in red below.	

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

Rule 11. (1) The board approves and adopts by reference the complete list of drugs and other substances that are considered controlled substances under the ~~Controlled Substance Act (~~CSA~~)~~ ~~of 1970, 21 USC 801~~, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15, except for **the following:**

(a) ~~those drugs~~**Drugs** or other substances ~~specifically~~ **scheduled, rescheduled, or descheduled** ~~excepted~~ by this state’s laws enacted after ~~the effective date of these rules~~**January 6, 2022.** ~~or as~~

(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.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm~~ **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 ~~scheduled~~**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),**	**x**				

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.** **(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 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**	**x**				

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**					**x**

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 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~~, which includes the optical, position, and geometric isomers~~.**	**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**			

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

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

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

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

(e) Pentazocine is a schedule 4 controlled substance.

(f) Brorphine is a schedule 1 controlled substance.

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

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

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

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

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

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

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

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

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

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

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

~~(II) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids.~~
~~(III) Is packaged with a prominent label securely affixed to each package that includes all of the following:~~
~~(1) The amount in milligrams of ephedrine in a serving or dosage unit.~~
~~(2) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.~~
~~(3) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable regulations adopted by the FDA.~~
~~(4) That improper use of the product may be hazardous to an individual's health.~~

Board Response	

Rule 338.3132 Controlled substance license.

Section Numbers	Commenter	Comment
(5) and (7)	O'Connor	There are revisions to the protocol required for licensure for CS research and analytical labs. References to some of the CFR's are not needed as these do not apply and the inclusion causes confusion. The suggested edits are below to eliminate confusion of what is required: (5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**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:** ~~is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~: **(i) Investigator:** **(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) Research project:** **(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) Authority:** **(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.** (7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with ~~his or her~~**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:** ~~is filed and approved by the FDA and the DEA pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~ **(i) Investigator:** **(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) Chemical analysis project:** **(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) Authority:** **(a) Institutional approval.** **(b) Approval of a Human Research Committee for human studies.** **(c) Indication of an approved funded grant (number), if any.**

Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.

R 338.3132 Controlled substance license.

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

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, an applicant's license ~~shall~~**must** be verified by the licensing agency of ~~any~~**a** state ~~of the United States in which~~ **where** the applicant holds or has ever held a controlled substance license. This includes, but is not limited to, showing proof of ~~any~~ disciplinary action taken or pending against the applicant.

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

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

(b) Manufacturing and distributing a controlled substance **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 ~~pursuant to~~**under** ~~the provisions of~~ 21 CFR 1301.18 ~~and submitted to the department with the application for licensure~~.

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

(e) Conducting research with a controlled substance listed in schedules 2 to 5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity ~~who~~ **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 ~~who~~ **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 ~~any~~**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 ~~who~~ **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 ~~pursuant to~~**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 ~~when~~**if** the **license issued under** article 15 ~~license~~ **of the code, MCL 333.16101 to 333.18838** is renewed and the controlled substance license is renewed for an equal number of years ~~as the article 15 license~~.

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**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:**~~is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~ ~~i~~

(i) Investigator:

(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) Research project:

(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) Authority:

(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 ~~his or her~~ **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 ~~his or her~~**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~~s filed and approved by the FDA and the DEA pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~

(i) Investigator:

(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) Chemical analysis project:

(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) Authority:

(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 ~~any~~**a** licensed pharmacy in this state.

Board Response	

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

Section Numbers	Commenter	Comment
(1), (2), (5)	O'Connor	Due to the federal requirement of 8 hours of training for substance abuse and controlled substances, and the state's direction to accept the 8 hours training in lieu of the training required in this rule until the rule is modified, the rule language needs to be corrected to edit the training content for those licensees who are required to obtain a DEA registration in subrule(1)(a) to include only utilizing the MAPS and State and federal laws regarding prescribing and dispensing controlled substances. The rule also needs to require others who do not get the DEA registration to meet all the subjects in the current rule and require the training for each cycle, not just a 1-time training. **Suggested Edits are highlighted in red.** Rule 35. (1) An individual who is applying for **or renewing** a controlled substance license ~~or who is licensed to prescribe or dispense controlled substances pursuant to~~**under** ~~section 7303 of the code, MCL 333.7303,~~ shall complete a ~~1-time~~ training in opioids and controlled substances awareness **before applying for the license or renewal. The training must meet** ~~that meets~~ the following standards: (a) Training content must cover ~~all~~**both** of the following topics: ~~(i) Use of opioids and other controlled substances.~~ ~~(ii) Integration of treatments.~~ ~~(iii) Alternative treatments for pain management.~~ ~~(iv) Counseling on the effects and risks associated with using opioids and other controlled substances.~~ ~~(v) The stigma of addiction.~~ ~~(vi)~~ Utilizing the MAPS. ~~(vii)~~ **(ii)** State and federal laws regarding prescribing and dispensing controlled substances. ~~(viii) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.~~ (b) Topics covered under subrule (1)(a) of this rule may be obtained from more than 1 program. (c) Acceptable providers or methods of training include ~~any of~~ the following: (i) Training offered by a nationally recognized or state-recognized health-related organization. (ii) Training offered by, or in conjunction with, a state or federal agency. (iii) Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the code, MCL 333.16101 to 333.18838. (iv) Training obtained in an educational program that has been approved by a board established under article 15 of the code, MCL 333.16101 to 333.18838, for initial licensure or registration, or by a college or university. (d) Acceptable modalities of training include ~~any of~~ the following: (i) Teleconference or webinar.

		(ii) Online presentation. (iii) Live presentation. (iv) Printed or electronic media. (2) A prescriber or dispenser ~~shall~~**may** ~~not~~ delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with ~~subrules~~ **subrule** ~~(1) and~~ (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule. (3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, an individual shall provide an acceptable proof of completion of training, including ~~either~~**1** of the following: (a) A completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name. (b) A self-attestation by the individual that includes the date, provider name, name of training, and individual's name. (4) An individual who has been issued a controlled substance license ~~pursuant to~~**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 ~~his or her~~**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 an applicant provides proof of having completed the controlled substance training. (5) ~~Beginning December 31, 2021,~~ **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 ~~the~~ **a** controlled substance training ~~required by subrule (1) of this rule.~~ **The training must be taken one time during the current license cycle. The training must cover ~~that covers~~ all 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.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

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 or ~~who~~ ~~is licensed to prescribe or dispense controlled substances pursuant to~~**under** ~~section 7303 of the code, MCL 333.7303,~~ shall complete a ~~1-time~~ training in opioids and controlled substances awareness ~~that meets~~ **before applying for the license or renewal. The training must meet** the following standards:

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

(i) ~~Use of opioids and other controlled substances.~~

~~(ii) Integration of treatments.~~

~~(iii) Alternative treatments for pain management.~~

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

~~(v) The stigma of addiction.~~

~~(vi)~~ Utilizing the MAPS.

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

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

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

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

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

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

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

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

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

(i) Teleconference or webinar.
(ii) Online presentation.
(iii) Live presentation.
(iv) Printed or electronic media.

(2) A prescriber or dispenser ~~shall not~~ **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 ~~subrules~~ **subrule** ~~(1) and~~ (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, ~~an~~ **the** individual shall provide an acceptable proof of completion of training, including ~~either~~**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 ~~pursuant to~~**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 ~~his or her~~**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 ~~an~~ **the** applicant provides proof of having completed the controlled substance training.

(5) ~~Beginning December 31, 2021,~~ **Except as expemted 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 ~~the~~ **a** controlled substance training ~~required by subrule (1) of this rule~~. **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.

Board Response	

Rule 338.3141 Thefts and diversions.

Section Numbers	Commenter	Comment
Subrule 3	Baran	The DEA has set a time period when the registrant must file the 106 form which is different from the state requirement. "21 USC 1301.74 (c) ….The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss . . . ." **Suggested Change:** To be less confusing for licensees change the 15 days to 45 days.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

Board Response	

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 ~~15~~ **45** days ~~of~~ **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 ~~person~~**individual** is identified and action is taken against ~~him or her~~**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.

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

Section Numbers	Commenter	Comment
Subrule 3	Baran	Controlled substance prescriptions must be kept on site. 21 CFR 1304.04(h) states paper prescriptions for Schedule II, III, IV and V controlled substances shall be maintained at the registered location in a separate prescription file. Deleting the on site would conflict with federal rules. **Suggested Change:** Leave on site in the rule.
Subrule 6	Baran	Schedule 2 order forms and controlled substance inventories are required by federal law to be stored at the pharmacy. Controlled substances in the automated dispensing system (ADS) belong to the pharmacy because the drugs are not considered dispensed until the ADS provides them, thus drugs in the ADS are counted as pharmacy inventory. Schedule 2 order forms (DEA 222 form) used to order the 2s for the ADS location belong to the pharmacy. The ADS at a different address than the pharmacy is not a pharmacy. See LARA's licensing guide for Controlled Substance Automated Device License. **Suggested Change:** Delete (6). The pharmacy is already required to maintain executed DEA 222 forms and controlled substance inventories. See Rule 338.3151(5) and 338.3153(1).
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

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

Rule 53. **(1)** For 2 years, a licensee shall maintain in the pharmacy ~~responsible for the automated device,~~ for review by the department, an agency, or the board, all records for controlled substances, including invoices~~,~~ **and** acquisition records~~, and sales receipts,~~ as follows:

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

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

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

(~~d~~**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.

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

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

~~(g)~~**(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.

~~(h)~~**(3)** ~~The~~**A** licensee shall keep the original prescription record on site for 5 years ~~from~~**after** the last date of dispensing. However, ~~after~~ 2 years ~~from~~**after** the last date of dispensing, ~~if an electronic duplicate is made of the original paper prescription, which becomes the original prescription, the original prescription may be destroyed~~ **a licensee may make an electronic duplicate of the original paper prescription, which becomes the original prescription**.

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

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

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

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

(~~iv~~**d**) Date the controlled substances were distributed.

(j5) A DEA 222 order form must be used for schedule 2 drugs.

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

~~(6) A pharmacy that holds an additional license for an automated dispensing system that dispenses controlled substances shall store inventories and schedule 2 order forms at the licensed location of the automated device.~~

Board Response	

Rule 338.3161 Controlled substance prescriptions.

Section Numbers	Commenter	Comment
(1)(b) and (6)	Chludzinski	R 338.3161(1)(b) does not require the prescriber's professional designation to be on a prescription, but R 338.3161(6) states that the professional designation must be stored electronically. If the prescriber isn't required to supply a professional designation on a prescription, how will a pharmacy identify and store it?
(6)	Baran	Stored electronically is vague. It could be stored in a separate computer or in a separate word file from the pharmacy's automated data processing system. **Suggested Change:** The professional designation for the prescribing practitioner must be stored electronically in the pharmacy's automated data processing system.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

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** ~~must contain~~**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, ~~then~~ 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 ~~shall~~**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, ~~but,~~ **however,** ~~pursuant to~~**under** ~~the code~~**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 ~~pursuant to~~**under** a prescription not prepared in the form required by these rules is liable ~~pursuant to~~**under** the code.

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

~~**(6) The professional designation for the prescribing practitioner must be stored electronically.**~~

Board Response	

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

Section Numbers	Commenter	Comment
	Baran	Section 333.17754 no longer applies. Rule revised to meet 333.17754a. **Suggested Change:** R 338.3162a Electronic transmission of prescription; waiver of electronic transmission. Rule 62a. (1) ~~Until the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted~~

		~~prescription, if all of the following conditions are satisfied:~~ **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 controlled substance prescription under R 338.3161. (c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription. (d) All requirements in section 17754**a** of the code, MCL 333.17754**a**, are met. (2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription. (3) ~~Effective **on** the enforcement date established by the federal Centers for Medicare and Medicaid Services**CMS** for the Medicare electronic transmission requirement, prescribers shall, unless an exception under section 17754a of the Code, **code**, MCL 333.17754a, applies, electronically transmit a prescription for a controlled substance consistent with both of the following requirements:~~ ~~(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.~~ ~~(b) All the requirements in R 338.3161 are met.~~ ~~(4)~~ A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy either of the following requirements:

		(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the ~~federal Centers for Medicare and Medicaid Services~~**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 prescription is dispensed by a dispensing prescriber.~~ 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 ~~Federal Centers for Medicare and Medicaid Services~~**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**~~Intention to cease practice within the next twelve months~~. (C) Limited practice due to an illness or other unforeseen event. ~~(iv)~~**(iii)** The prescriber issues prescriptions from a ~~non-profit charitable~~ **not-for-profit** medical clinic **that provides free or low-cost services to the public**. ~~(5)~~ (4)A waiver is valid for 2 years and ~~is applicable~~**applies** to the specific circumstances included in the application. A waiver may be renewed by application to the department.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

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

Rule 62a. (1) ~~Until the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:~~ **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 17754 of the code, MCL 333.17754, are met.

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

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

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

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

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

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

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

~~(iii)~~**(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 ~~Federal Centers for Medicare and Medicaid Services~~**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**~~Intention to cease practice within the next twelve months~~.

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

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

~~(5)~~**(4)** A waiver is valid for 2 years and ~~is applicable~~**applies** to the specific circumstances included in the application. A waiver may be renewed by application to the department.

Board Response	

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

Section Numbers	Commenter	Comment
Subrule (1)(a)(i)	Baran	To add tribal government identification **Suggested Change:** (a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply: (i) An identification number, as specified in R 338.3102~~(1)~~(~~f~~**h**)(iv)(A) to (~~C~~**E**), is not required for patients under the age of 16.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

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

Rule 62b. (1) Except as otherwise exempt under section 7333a of the code, MCL 333.7333a, a pharmacist, dispensing prescriber, ~~and~~ **or** veterinarian licensed under ~~Part~~ **part** 177 of the code, MCL 333.17701 to 333.17780, who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by ~~the~~ **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. ~~For purposes of~~**As used in** this subdivision, all of the following apply:

(i) An identification number, as specified in R 338.3102~~(1)(f)(iv)~~**(h)**(A) to (~~C~~**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(1)(f)(iv).~~ **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.** ~~of issue of the prescription.~~

(k) The date ~~of dispensing~~**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 ~~pharmacy~~ **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, ~~or~~ a patient's representative, or veterinarian's client is correct.

(3) As used in this rule, R 338.3162c, and R 338.3162d, ~~the term~~ "dispense" or "dispensing" means the preparation, compounding, packaging, or labeling of a controlled substance along with delivery of the controlled substance ~~pursuant to~~**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, ~~the term~~ "patient" ~~refers to~~ **means** an individual, not an animal.

Board Response	

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

Section Numbers	Commenter	Comment
Subrule (2)	Baran	To bring it current with ASAP standard. **Suggested Change:** (2) The data must be transmitted in the format established by the ASAP ~~4.1~~ 5 Standard for Prescription Drug Monitoring Programs.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

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

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

(2) The data must be transmitted in the format established by the ASAP ~~4.1~~5 Standard for Prescription Drug Monitoring Programs.

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

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

Board Response	

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

Section Numbers	Commenter	Comment
Subrule (1)	Baran	DEA under 1306.11(d) only allows a written prescription for an oral emergency prescription not an electronic

		prescription. **Suggested Change:** (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~~ ~~pursuant to~~**under** R 338.3162a. (c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** ~~either~~ a written prescription ~~or a prescription transmitted electronically~~.
Rules Committee Response	The committee elected not to make the suggested change as the code allows both options.	

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

Rule 65. (1) ~~Within 7 days after~~**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 ~~pursuant to~~**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) ~~Upon receipt of the prescription, the~~ **After the** dispensing pharmacist **receives the prescription the pharmacist** shall attach the prescription to the oral order ~~which~~**that** was earlier reduced to writing.

(c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **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 ~~pursuant to~~**under** subrule (1) of this rule voids the authority conferred by this rule.

Board Response	

Rule 338.3183 Distribution to suppliers.

Section Numbers	Commenter	Comment
Entire Rule	Baran	The rule is confusing. If the intent of this rule is to allow a licensee to return controlled substances from whom they obtained the drug lawfully it is already allowed under R 338.3153.

		Suggested Change: Delete entire rule.
Rules Committee Response	The committee elected not to make the suggested change as R 338.3153 does not adequately handle the content of this rule.	

R 338.3183 Distribution to suppliers.

Rule 83. (1) A**n** ~~person~~ **individual** who is lawfully in possession of a controlled substance that is listed in ~~any~~**a** schedule may ~~distribute~~**return** the substance to the ~~person~~ **individual who gave the person** ~~from whom he or she obtained~~ the substance or to the manufacturer of the substance without obtaining a license to distribute. The ~~person~~ **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, ~~if any,~~ of the ~~person~~ **individual** who ~~makes the distribution~~**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.

Board Response	