MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
OCTOBER 7, 2020

The Michigan Board of Pharmacy Rules Committee Work Group, met on October 7, 2020. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman called the meeting to order at 9:31 a.m.

ATTENDANCE

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

Members Absent: Cynthia Boston, BHS, R.Ph.T.

Staff Present: Andria Ditschman, Senior Policy Analyst, Boards and Committees Section
Jacob Poynter – Analyst – Licensing Division
Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Rose Baran – Self
Farah Jalloul – Michigan Pharmacists Association
Lisa Penny – Spectrum Health

WELCOME

RULES DISCUSSION

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

R 338.3102 Definitions; I to P.

Subdivision (1)(f) "Patient identifier"

Mollien stated that this was cleaned up and easy to read.

R 338.3104 Definitions; R, S.

Ditschman stated that words "scientific investigator" were removed as the term was not used in the rules and the definition was not referenced in the Code.

Part 2. Schedules

Ditschman stated that the schedules were reviewed by one of the Bureau's staff pharmacists. She stated that substances were added that were scheduled in the Code or rules differently than in the federal schedules; and that the date in subrule (1) would be added to make sure that the most current version of the federal schedules were referenced.

Mollien stated that the set-up was good. He understood that it may take several reviews to make sure it was accurate and that the exceptions were correct.

Sleiman and Taylor agreed with Mollien.

Subdivision (3)(d): Jalloul asked if over the counter (OTC) needed to be addressed specifically as it was addressed in the statute.

Mollien stated that it did not need to be addressed because it was over the counter. Language in the rules was not meant to be repetitive of what is already listed in the statute. He also stated that the language should be removed from the statute.

Ditschman clarified that a user would reference the federal schedule first followed by the administrative rules for any differences.

Baran stated that pentazocine was a schedule 3 drug in Michigan but listed as a schedule 4 federally.

Ditschman asked if this should be changed in the rules.

Mollien stated that it should be changed to align with the federal schedule.

Ditschman stated that by aligning pentazocine with the federal schedule, it would not be listed in the rules as the rules will now adopt the federal schedule.

Taylor asked if propofol should be scheduled in the rules. It was treated as a controlled substance with storage and documentation although it was not one. It is a highly abused drug, even within hospital settings.

Mollien asked if it was abused or misused.

Taylor stated that it could be considered diversion. She stated that it should be scheduled at a 4 or 5 but she would need to look at the actual guidelines for each. She stated that national recommendations were to treat it as a controlled substance.

Ditschman stated that MCL 333.7201, required the Board to look at the potential for abuse, scientific affects, patterns of abuse, and history of abuse.

Taylor stated that history of abuse/misuse could be used for propofol.

Mollien suggested that evidence should be collected and brought before the Board for scheduling when the Board reviewed the rules. He stated it would probably fall under a schedule 5.

Taylor stated that she would collect information and provide it to Ditschman.

R 338.3132 Activities requiring separate licenses.

Ditschman stated that she considered setting up a chart for this rule, but that a chart was confusing. Therefore, she tried to make sure that she simply clarified the subrules.

Ditschman stated that the word “person” was defined as a person or entity. So, using the term “person” was confusing throughout the rule. The statute uses “prescriber”, but the rule uses “physician or prescriber”. She stated she would work with the Department to use consistent terms.

Mollien stated that the rule needed to be simplified as much as possible.

Ditschman stated that the rule could specify the professions (dentist, physician, etc.), pharmacist, and manufacturer. The confusion was being able to identify the “who” and if two or more licenses are needed for different uses of controlled substances.

Taylor suggested using the term LIP to identify a licensee.

Sleiman suggested using “individual” or “entity” instead of person.

Mollien stated that there were situations where an additional license would be needed.

Poynter stated that it was confusing when all facilities aren’t licensed such as a surgical center due to storage. He stated that they should be licensed as well.

Taylor agreed with Poynter. She stated that licensing the facility would be helpful and that oversight would also come from the DEA.

Poynter stated that using a chart in this rule could be a concern when it did not address the drug control license.

Ditschman asked if there was a reason for an individual, who was a licensed pharmacist and a licensed dentist, to have two controlled substance licenses.

Poynter stated that it did not happen often, but when it did, the individual typically obtains two licenses because the renewal cycle of the controlled substance was tied to the renewal of the professional license. He stated that it did not make sense to obtain two controlled substance licenses as the controlled substance license moves with the individual, it was not tied to an address. He stated that there was no specific rule that stated one or two licenses were needed in this scenario.

Ditschman questioned if there was discipline on the controlled substance licensed tied to one professional license, would it affect the controlled substance license tied to the other professional license.

Poynter stated that he was not sure, but the action should apply to both.

Mollien stated that if the statute did not require two controlled substance licenses, the rules should not either.

Ditschman stated that the statute stated that the controlled substance license was tied to the professional license and the professional license term.

Poynter stated that, based on the statutory language, two licenses would be required as the professional licenses have different renewal periods.

Ditschman will follow up with the Department for further clarification or an addition to the rules.

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

Ditschman stated that there were no new changes made to this rule.

Mollien asked about the length of time the proof needed to be maintained.

Ditschman stated that proof would have to be provided at the time of an audit. Audits were conducted randomly, so there would be no way to know when, or if, proof of training would have to be provided.

Mollien asked why the audit would not happen sooner so that the proof could be provided sooner. He stated it seemed unreasonable.

Poynter stated that eventually initial licensees will have to provide proof of the training before being issued a controlled substance license. Therefore, maintaining proof would only apply to those who already have a controlled substance license.

Ditschman asked the Department was currently requiring for proof of training.

Poynter stated that, at this time, for renewal, it is an attestation.

Ditschman read the language from the statute and it indicated that this requirement could be audited. Ditschman stated she would follow up with the Department about a possible plan to provide an end date on auditing due to providing proof at the time of initial licensure.

Taylor stated that she agreed with Mollien that keeping the proof indefinitely, in the possible event of a random audit, is unreasonable.

R 338.3136 Information in applications.

Ditschman stated that information from this rule should be added to R 338.3132 to simplify the rules.

R 338.3137 Waiver of license requirements.

Ditschman stated that the information in subdivisions (a), (b), (c), (d), and (e) along with subrules (2) and (3) were the same as language in statute.

Mollien stated that they should all be removed.

The Rules Committee agreed to remove the above noted sections.

R 338.3141 Thefts and diversions.

Ditschman stated that the Department did not agree with limiting notification of only a “significant” loss.

Taylor stated that the questions of what is “significant” occurs every day.

Ditschman asked who determines what was “significant.”

Mollien stated that the rules should adopt the same criteria for loss as the DEA.

Subrule (4): Ditschman stated that she changed this subrule to 15 days.

Subrule (3): Mollien stated that the 106 form was used at the end of an investigation. The Department should receive the same notification as the DEA. Use "1 business day of the suspected loss."

Taylor questioned if reporting within 1 business day was being done.

Ditschman asked if it should read "Within 1 business day following discovery of a suspected theft or a significant loss…." The rules should provide criteria of what was considered a "significant loss."

Mollien stated that "significant" as used by the DEA needed to be used in this rule.

Subrule (4): Mollien stated that the 106 form cannot be used for the state reporting as it is a federal form and falls under their jurisdiction. Mollien stated using "equivalent document" was sufficient.

Penny asked if notification needed to be done if the 106 form was not submitted at the end of the investigation. Is a statement that the investigation was closed sufficient?

Mollien stated that a statement would be sufficient regarding the closing of an investigation.

Penny asked if the wording "whether or not" covered providing a notification/statement.

Mollien stated that it did because some form of follow-up would be needed. The state would need something showing that the investigation was closed due to no reportable loss.

Andria asked Penny if "whether or not" covered her reporting question.

Penny confirmed that it did.

R 338.3143 Storage of controlled substances.

Subrule (3): Ditschman stated that she was unable to locate the federal requirements that are similar to the requirements for this rule.

Taylor stated that the substances in the rule were very rarely used, and this was outdated language.

Ditschman asked if some form of language was important to use regarding locked storage.

Taylor stated it was not.

Baran asked if they were treated the same as Ativan.

Taylor stated that was exactly what was done.

Subrule (1): Ditschman asked if the language should be changed from “cabinet” to “cabinet or refrigerator.” The Rules Committee said that if “cabinet” could be read generally, then “refrigeration” did not need to be added.

Taylor asked what exactly was considered a “cabinet.” Could a vault be considered a “cabinet?”

Mollien stated that the rule required the minimal requirement for storage.

Ditschman asked if the word “anchored” was necessary.

The Rules Committee stated that it was not.

Ditschman will remove subrule (3) if refrigeration was covered in subrules (1) and (2).

R 338.3145 Employees; disqualification.

Ditschman stated she that the Department was not recommending changes at this time and asked the Rules Committee if there were concerns with the way the rule was written.

Mollien stated that there were no red flags for him.

Subdivision (1)(c): Mollien asked whether a licensee, who had a disciplined controlled substance license in another state, even if the discipline is cleared up, would be disqualified for licensure in Michigan.

Ditschman clarified that this provision referenced only those individuals with active discipline in another state.

R 338.3151 Inventories

Subrule (9): Ditschman stated that this subrule was created to include the requested PIC language.

Mollien stated that the subrule was clearly written.

Subrule (4): Baran stated that hospitals do not have a beginning or close of day, so the rule should provide for a time.

Mollien and Taylor agreed as that would also apply for 24-hour retail pharmacies.

Ditschman suggested adding that as a new subrule as opposed to adding the language to each subrule.

Mollien agreed.

ADJOURNMENT

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

Prepared by:
Stephanie Wysack, Board Support October 15, 2020
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY – CONTROLLED SUBSTANCES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the board of pharmacy by sections **7106, 7109,** 7201, **7203, 7216,** 7219, 7301, **7303, 7303a, 7321, 7333, 7333a,** ~~and~~ 16204e**, and 17754** of **the public health code,** 1978 PA 368, **MCL 333.7106, 333.7109,** ~~MCL~~ 333.7201, **333.7203, 333.7216,** 333.7219, 333.7301, **333.7303, 333.7303a, 333.7321, 333.7333, 333.7333a,** ~~and~~ 333.16204e**, 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 338.3108, R 338.3111, R 338.3132, R 338.3135, R 338.3136, R 338.3137, 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 338.3163, R 338.3165, R 338.3167, R 338.3170, R 338.3181, and R 338.3185 of the Michigan Administrative Code are amended, R 338.3109, R 338.3112, R 338.3113, R 338.3113a, R 338.3114, R 338.3114a, R 338.3116, R 338.3117, R 338.3118, R 338.3119, R 338.3119a, R 338.3119b, R 338.3120, R 338.3121, R 338.3121a, R 338.3122, R 338.3123, R 338.3125, R 338.3126, R 338.3127, R 338.3129, R 338.3136, R 338.3152, R 338.3162e, and R 338.3182 are rescinded as follows:

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

(a) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.

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

~~(a)~~ **(c)** ~~"Act"~~ **"Code"** means 1978 PA 368, MCL 333.1101 ~~et seq.~~ **to 333.25211.**

~~(b) "Deleterious drug" means a drug, other than a proprietary medicine, that is likely to be destructive to adult human life in quantities of 3.88 grams or less.~~

~~(c)~~ **(d)** "Department" means the department of ~~community health~~ **licensing and regulatory affairs**.

~~(d)~~ **(e)** "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures nonrepudiation so that the signature may not be rejected based on its validity.

R 338.3102 Definitions; I to P.

Rule 2. (1) As used in these rules:

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

(b) "Licensee" means a person who is licensed pursuant to section 7303 of the ~~act~~ **code**.

(c) "Michigan automated prescription system (~~maps~~**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~~ **American Society for Automation in Pharmacy** (~~asap~~**ASAP**) and contains the information specified in R 338.3162b.

(d) "National drug code number (~~ndc~~ **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~~ **Federal Food, Drug, and Cosmetic Act**.

(e) "Officer" means a **federal,** state, county, or local law enforcement officer who has a duty to enforce the laws of this state.

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

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

(iv) Any 1 of the following **identification numbers**:

(A) A ~~Michigan~~ **state issued** driver's license number **obtained from a state issued driver's license**.

(B) ~~An~~ **A state issued** identification number obtained from a **state issued** photo identification card ~~issued by the state of Michigan~~.

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

~~(C)~~ **(D)** The number zero. Zeroes shall be entered as the identification number, if the positive identification presented by the patient or the patient's agent or caregiver does not include a license number or an identification number, as listed in subparagraphs (A) and ~~(B)~~ **(C)** of this paragraph**, or the patient is under the age of 16**.

(g) "Positive identification" means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency, provided the identification card meets the requirements of this rule. **If the medication being dispensed is for an animal,**

positive identification means the animal's description and identification of the individual requesting treatment for the animal, that meets the requirements of subdivision (f)(i) to (iv).

~~(2) As used in part 5 of these rules:~~

~~(a)~~ **(h)** "Medical institution" means **the term as defined in R 338.486** ~~an inpatient health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services~~.

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

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

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

(b) "Scientific investigator" means a person, other than a physician, who is licensed to conduct research with a controlled substance listed in schedules 1 to 5.

~~(c) "Sign" means to affix a signature manually in the same manner as signing a check or legal document or to use an electronic signature, as defined in subdivision (d) of R 338.3101. Stamped signatures are not valid for any controlled substance prescription.~~

~~(d)~~ **(c)** "Substance" means a controlled substance unless the context indicates otherwise.

R 338.3108 Terms defined in ~~act~~ **code**.

Rule 8. **Unless otherwise defined in these rules, the** ~~Terms~~ **terms** defined in the ~~act~~ **code** have the same ~~meanings~~ **meaning** when used in these rules.

R 338.3109 ~~Rescission.~~ **Rescinded.**

~~Rule 9. Rules 14, 21, and 22 of the board, being R 338.484, R 338.491 and R 338.492 of the Michigan Administrative Code~~**administrative code** ~~and appearing on pages 2880 and 2885 of the 1963 Annual Supplement of the Code~~ **code**~~, are rescinded.~~

PART 2. SCHEDULES

R 338.3111 ~~Schedule 1; opiates~~ **Schedules; adopt federal controlled substance schedules 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 substance under the Controlled Substanced Act (CSA) that have been divided into five schedules as published in Title 21 CFR sections 1308.11 to 1308.15 ( ) except for those drugs or other substances specifically excepted by this state's laws or as listed in subrule (3).**

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm, or at ten 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, MI 48909.

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

(a) Marijuana including pharmaceutical-grade cannabis, as those terms are defined in part 71 and part 81 of the code, 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 authorized 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 authorized 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) Propofol is a schedule ___ controlled substance.

(g) Brorphine is a schedule ___ controlled substance.

(g) Except as otherwise provided in subdivision (e) of this rule, 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) The following are not included in schedule 5:

(i) A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine if the drug product may lawfully be sold over the counter without a prescription under federal law, is labeled and marketed in a manner consistent with the pertinent over the counter tentative final or final monograph, is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement and if 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, 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:

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

(2) It does not contain hydrochloride or sulfate salts of ephedrine alkaloids.

(3) It is packaged with a prominent label securely affixed to each package that states all of the following:

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

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

(c) 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 provided in applicable regulations adopted by the FDA.

(d) That improper use of the product may be hazardous to a person's health.

~~Unless, the following opiates including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, when the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, are included in schedule 1:~~

~~(a) Acetyl-alpha-methylfentanyl.~~

~~(b) Acetylmethadol.~~

~~(c) Allylprodine.~~

~~(d) Alphacetylmethadol, except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.~~

~~(e) Alphameprodine.~~

~~(f) Alphamethadol.~~

~~(g) Alpha-methylfentanyl.~~

~~(h) Alpha-methylthiofentanyl.~~

~~(i) Benzethidine.~~

~~(j) Betacetylmethadol.~~

~~(k) Beta-hydroxyfentanyl.~~

~~(l) Beta-hydroxy-3-methylfentanyl.~~

~~(m) Betameprodine.~~

~~(n) Betamethadol.~~

~~(o) Betaprodine.~~

~~(p) Clonitazene.~~

~~(q) Dextromoramide.~~

~~(r) Diampromide.~~

~~(s) Diethylthiambutene.~~

~~(t) Difenoxin.~~

~~(u) Dimenoxadol.~~

~~(v) Dimepheptanol.~~

~~(w) Dimethylthiambutene.~~

~~(x) Dioxaphetyl butyrate.~~

~~(y) Dipipanone.~~

~~(z) Ethylmethylthiambutene.~~

~~(aa) Etonitazene.~~

~~(bb) Etoxeridine.~~

~~(cc) Furethidine.~~

~~(dd) Hydroxypethidine.~~

~~(ee) Ketobemidone.~~
~~(ff) Levomoramide.~~
~~(gg) Levophenacylmorphan.~~
~~(hh) MPPP(1-methyl-4-phenyl-4-propionoxypiperidine).~~
~~(ii)3-methylfentanyl(n-(3-methyl-1-2-phenylethyl)-4- piperidyl)-n-phenylpropanamide).~~
~~(jj) 3-Methylthiofentanyl.~~
~~(kk) Morpheridine.~~
~~(ll) Noracymethadol.~~
~~(mm) Norlevorphanol.~~
~~(nn) Normethadone.~~
~~(oo) Noripipanone.~~
~~(pp) Para-fluorofentanyl.~~
~~(qq) PEPAP(1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine.~~
~~(rr) Phenadoxone.~~
~~(ss) Phenampromide.~~
~~(tt) Phenomorphan.~~
~~(uu) Phenoperidine.~~
~~(vv) Piritramide.~~
~~(ww) Proheptazine.~~
~~(xx) Properidine.~~
~~(yy) Propiram.~~
~~(zz) Racemoramide.~~
~~(aaa) Thiofentanyl.~~
~~(bbb) Tilidine.~~
~~(ccc) Trimeperidine.~~

~~R 338.3112 Schedule 1; opium derivatives.~~ **Rescinded.**
~~Rule 12. Unless specifically excepted, the following opium derivatives, their salts, isomers and salts of isomers, when the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation, are included in schedule 1:~~

~~Substance~~	
~~a~~	~~Acetorphine~~
~~b~~	~~Acetyldihydrocodeine~~
~~c~~	~~Benzylmorphine~~
~~d~~	~~Codeine methylbromide~~
~~e~~	~~Codeine-N-Oxide~~
~~f~~	~~Cyprenorphine~~
~~g~~	~~Desomorphine~~
~~h~~	~~Dihydromorphine~~
~~i~~	~~Drotebanol~~
~~j~~	~~Etorphine (except hydrochloride salts)~~
~~k~~	~~Heroin~~
~~l~~	~~Hydromorphinol~~
~~m~~	~~Methyldesorphine~~
~~n~~	~~Methyldihydromorphine~~

o	Morphine methylbromide
p	Morphine methylsulfonate
q	Morphine-N-Oxide
r	Myrophine
s	Nicocodeine
t	Nicomorphine
u	Normorphine
v	Pholcodine
w	Thebacon

R 338.3113 Schedule 1; hallucinogenic substances. **Rescinded.**

Rule 13. Unless specifically excepted, any material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules II through V, is not approved by the federal food and drug administration as a drug, and contains any quantity of the following hallucinogenic substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), whenever the existence of these salts, isomers, homologues (analogs) and salts of isomers and homologues (analogs) is possible within the specific chemical designation, is included in schedule 1:

	Substance	Trade or Other Names
a	1-(1-(2-thienyl)cyclohexyl)pyrrolidine	TCPY
b	2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine	2C-E
c	2-(2,5-Dimethoxy-4-methylphenyl)ethanamine	2C-D
d	2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine	2C-P
e	2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine	2C-N
f	2-(2,5-Dimethoxyphenyl)ethanamine	2C-H
g	2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine	2C-C
h	2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine	2C-T-2
i	2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine	2C-I
j	2-[(4-Isopropylthio)-2,5-dimethoxyphenyl)]ethanamine	2C-T-4
k	2,5-dimethoxy-4-ethylamphetamine	DOET
l	2,5-dimethoxy-4-(n)-propylthiophenethylamine	2C-T-7
m	2,5-dimethoxyamphetamine	• 2,5-dimethoxy-alpha-methylphenethylamine • 2,5-DMA
n	3,4-methylenedioxy-n-ethylamphetamine	
o	3,4-methylenedioxyamphetamine	
p	3,4-methylenedioxymethamphetamine	MDMA
q	3,4,5-trimethoxyamphetamine	
r	4-bromo-2,5-dimethoxphenethylamine	• 2-(4-bromo-2-5-dimethoxyphenyl)-1-aminoethae

		• desmethyl DOB • 2c-b • nexus
s	4-bromo-2,5-dimethoxyamphetamine	• 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine • 4 bromo-2,5-DMA
t	4-methoxyamphetamine	• 4-methoxy-alpha-methylphenethylamine • Paramethoxyamphetamine • PMA
u	4-methyl-2,5-dimethoxyamphetamine	• 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine • DOM • STP
v	5-methoxy-3,4-methylenedioxyamphetamine	
w	5-methoxy-N, N-diisopropyltryptamine	5-MeO-DiPT
x	5-methoxy-N, N-dimethyltryptamine	5-MeO-DMT
y	Alpha-ethyltryptamine	• etryptamine • monase • a-ethyl-1h-indole-3-ethanamine • 3-(2-aminobutyl)indole • a-et • AE
z	Bufotenine	• 3-(beta-dimethylaminoethyl)-5-hydroxyindole • 3-(2-dimethylaminoethyl)-5-indolol • N,N-dimethyserotonin • 5-hydroxy-N-N-dimethyltryptamine • mappine
aa	Diethyltryptamine	• N, N-Diethyltryptamine • DET
bb	Dimethyltryptamine	DMT
cc	Ethylamine analog of phencyclidine	• n-ethyl-1-phenylcyclohexylamine • (1-phenylcyclohexyl)ethylamine • n-(1-phenylcyclohexyl)ethylamine • cyclohexamine • PCE
dd	Ibogaine	• 7-Ethyl-

		6,6beta,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido • [1',2':1.2]azepino[5,4-b]indole • tabernanthe iboga
ee	Lysergic acid diethylamine	
ff	Marihuana	
gg	Mescaline	
hh	N-ethyl-3-piperidyl benzilate	
ii	N-hydroxy-3,4-methylenedioxyamphetamine	
jj	N-methyl-3-piperidyl benzilate	
kk	Parahexyl	• 3-hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6Hdibenzol[b,d]pyran • synhexyl
ll	Peyote	
mm	Psilocybin	
nn	Psilocyn	
oo	Pyrrolidine analog of phencyclidine	• 1-(1-phenylcyclohexyl)-pyrrolidine • PCPy • PHP
pp	Thiophene analog of phencyclidine	• 1-[1-(2-thienyl)-cyclohexyl]-piperidine • 2-thienyl-analog of phencyclidine • TPCP • TCP
qq	Any derivative of phenethylamine with single or multiple alkyl, halogen, alkoxy, or substituted C,S,N, or O groups on the aromatic ring and/or fused variations, with or without alkyl substituents on the ethylamine moiety and/or single or multiple alkyl, halogen, hydroxyl, or alkoxy including methoxybenzyl substitution which shall include but not be limited to, all of the following:	
i	1-(2,5-dimethoxy-4-idophenyl)-propan-2-amine	• DOI • 2,5-Dimethoxy-4-iodoamphetamine
ii	1-(4-Bromo-2,5-dimethoxyphenyl)-2-aminopropane	• DOB • 2,5-Dimethoxy-4-bromoamphetamine
iii	1-(4-Bromofuro[2,3-f][1]benzofuran-8-	• bromo-

	yl)propan-2-amine	benzodifuranylisopropylamine • bromo-dragonFLY
iv	1-(4-chloro-2,5-dimethoxy-phenyl)propan-2-amine	• DOC • 2,5-Dimethoxy-4-chloroamphetamine
v	2-(2,5-dimethoxy-4(methylthio)phenyl)ethanamine	• 2C-T • 4-methylthio-2,5-dimethoxyphenethylamine
vi	2-(2,5-dimethoxy-4-nitro-phenyl)ethanamine	• 2C-N • 2,5-Dimethoxy-4-nitrophenethylamine
vii	2-(4-chloro-2,50dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine	• 2C-C-NBOMe • 25C-NBOMe • 2,5-Dimethoxy-4-chloro-N-(2-methoxybenzyl)phenethylamine
viii	2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine	• 2C-I-NBOMe • 25I-NBOMe • 2,5-Dimethoxy-4-iodo-N-(2-methoxybenzyl)phenethylamine
ix	2-(7-Bromo-5-methoxy-2,3-dihydro-1-benzofuran-4-yl)ethanamine	2CB-5-hemiFLY
x	2-(8-bromo-2,3,6,7-tetrahydrofuro[2,3-f][1]benzofuran-4-yl)ethanamine	2C-B-FLY
xi	2-(10-Bromo-2,3,4,7,8,9-hexahydropyrano[2,3-g]chromen-5-yl)ethanamine	
xii	5-(2-Aminopropyl)-2,3-dihydrobenzofuran	5-APDB
xiii	5-(2-Aminopropyl)benzofuran	5-APB
xiv	5-(2-Aminopropyl)indole	5-IT
xv	5-methoxy-3,4-methylenedioxy-amphetamine	
xvi	6-(2-Aminopropyl)-2,3-dihydrobenzofuran	6-APDB
xvii	6-(2-Aminopropyl)benzofuran	6-APB
xviii	N-(2-Hydroxybenzyl)-4-iodo-2,5-dimethoxyphenethylamine	• 2C-INBOH • 25I-NBOH
xix	N-(2-Hydroxybenzyl-4-iodo-2,5-dimethoxyphenethylamine	2C-B-FLY-NBOME
xx	N-(2-Methoxybenzyl)-2-(3,4,5-trimethoxyphenyl)ethanamine	• Mescaline-NBOME • 3,4,5-trimethoxy-N-(2-methoxybenzyl) phenethylamine

R 338.3113a Schedule 1; depressants. **Rescinded.**

~~Rule 13a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers when the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation is included in schedule 1:~~

~~(a) Gamma-hydroxbutyric acid.~~

~~Some other names:~~

~~(i) GHB.~~

~~(ii) gamma-hydroxybutyrate.~~

~~(iii) 4-hydroxybutyrate.~~

~~(iv) 4-hydroxybutanoic acid.~~

~~(v) sodium oxybate.~~

~~(vi) sodium oxybutyrate.~~

~~(b) Mecloqualone.~~

~~(c) Methaqualone.~~

~~R 338.3114 Schedule 1; tetrahydrocannabinols.~~ **Rescinded.**

~~Rule 14. Synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis and synthetic substances, derivatives, and their isomers with similar chemical structure or pharmacological activity, or both, such as the following, are included in schedule 1:~~

—

~~Substance~~	
~~a~~	~~Δ1 cis or trans tetrahydrocannabinol and their optical isomers, excluding dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States food and drug administration.~~
~~b~~	~~Δ6 cis or trans tetrahydrocannabinol and their optical isomers.~~
~~c~~	~~Δ3,4 cis or trans tetrahydrocannabinol and their optical isomers. Since the nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions, are included.~~
~~d~~	~~Synthetic cannabinoids. As used in this subrule, "synthetic cannabinoids" includes any material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules II through V, is not approved by the federal food and drug administration as a drug, and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:~~
~~i~~	~~Any compound containing a 3-(1-naphthoyl)indole structure, also known as napthoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not~~

	~~limited to: JWH-007, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398, AM-1220, AM-2201, and WIN-55, 212-2.~~
~~ii~~	~~Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure, also known as napthylmethylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-175, JWH-184.~~
~~iii~~	~~Any compound containing a 3-(1-naphthoyl)pyrrole structure, also known as naphthoylpyrroles with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the pyrrole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-370, JWH-030.~~
~~iv~~	~~Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl) ethyl group, whether or not further substituted on the indene ring to any extent and whether or not substituted on the naphthyl ring to any extent. An example of this structural class includes, but is not limited to, JWH-176.~~
~~v~~	~~Any compound containing a 3-phenylacetylindole structure, also known as phenacetylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-8 (SR-18), JWH-250, JWH-203, JWH-251, and JWH-302.~~
~~vi~~	~~Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure, also known as cyclohexylphenols, with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted on the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP-47,497 (and homologues (analogs)), cannabicyclohexanol, and CP-55,940.~~
~~vii~~	~~Any compound containing a 3-(benzoyl)indole structure, also known as benzoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: AM-694, pravadoline (WIN-48,098), RCS-4, AM-630, AM-679, AM-1241, and AM-2233.~~
~~viii~~	~~Any compound containing a 11-hydroxy-Δ8-tetrahydrocannabinol structure, also known as dibenzopyrans, with further substitution on the 3-pentyl group by an~~

	alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkyethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group. Examples of this structural class include but are not limited to: HU-210, JWH-051, JWH-133.
ix	Any compound containing a 3-(L-adamantoyl)indole structure, also known as adamantoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the adamantyl ring system to any extent. An example of this structural class includes, but is not limited to, AM-1248.
x	Any other synthetic chemical compound that is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring cannabinoids that is not listed in schedules II through V and is not approved by the federal food and drug administration as a drug.

R 338.3114a Schedule 1; stimulants. **Rescinded.**

Rule 14a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers, is included in schedule 1:

Substance		Trade or Other Names
a	Aminorex	• aminoxaphen • 2-amino-5-phenyl-2-oxazoline • 4,5-dihydro-5-phenyl-2-oxazolamine
b	Cathinone	• 2-amino-1-phenyl-1-propanone • alpha-aminopropiophenone • 2-aminopropiophenone • norephedrone
c	Mephedrone	• 4-MMC • 4-methylmethcathinone • m-CAT
d	Methcathinone	• 2-methyiamino-1-phenylpropan-1-one • CAT • Ephedrone
e	Methylenedioxypyrovalerone	• 3,4-Methylenedioxypyrovalerone • MDPV • Methadrone
f	Fenethylline	
g	(□)cis-4-methylaminorex([(□)cis-4,5-dihydro-4-methyl-5phenyl-2-oxazolamine)	
h	N-ethylamphetamine	
i	N,N-dimethylamphetamine	• N,N-alpha-trimethyl-benzeneethanimine • N,N-alpha-trimethylphenethylamine

j	Synthetic cathinones. As used in this subrule, "synthetic cathinones" includes any material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules II through V, is not approved by the federal food and drug administration as a drug, and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:
i	Any compound containing a 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	Any 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	Any 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 any position of the ring system with an alkyl, haloalkyl, halogen, alkylenedioxy, or alkoxy group, whether or not further substituted at any position on the ring system to any extent. Examples of this structural class include, but are not limited to, mephedrone, methylone, and 3-fluoromethylone.

R 338.3116 Schedule 2; substances of vegetable origin or chemical synthesis. **Rescinded.**

Rule 16. (1) Unless specifically excepted, the following substances of vegetable origin, or independently derived by means of chemical synthesis or by combination of extraction and chemical synthesis, are included in schedule 2:

(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including all of the following:

Substance	
i	Raw opium
ii	Opium extracts
iii	Opium fluid extracts
iv	Powdered opium
v	Granulated opium
vi	Tincture of opium
vii	Codeine
viii	Ethylmorphine
ix	Etorphine hydrochloride
x	Hydrocodone
xi	Hydromorphone
xii	Metopon

xiii	Morphine
xiv	Oripavine
xv	Oxycodone
xvi	Oxymorphone
xvii	Thebaine

(b) A salt, compound, derivative, or preparation thereof which is chemically equivalent to or identical with a substance referred to in subdivision (a) of this subrule, except that these substances do not include the isoquinoline alkaloids of opium.

(c) Opium poppy, poppy straw, and concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form, which contains the phenathrine alkaloids of the opium poppy).

(d) Coca leaves, and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation which is chemically equivalent to or identical with any of these substances.

(e) Cocaine; its salts; isomers; whether optical, position, or geometric; and salts of isomers.

(2) Decocainized coca leaves or the extraction of coca leaves, which extractions do not contain cocaine or ecgonine, are specifically excepted from schedule 2.

R 338.3117 Schedule 2; opiates. **Rescinded.**

Rule 17. Unless specifically excepted, the following opiates, including their isomers, esters, and ethers, when the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, are included in schedule 2:

Substance		Trade or Other Names
a	Alfentanil	
b	Alphaprodine	
c	Anileridine	
d	Benzitramide	
e	Bulk propoxyphene (nondosage forms)	
f	Carfentanil	
g	Dihydrocodeine	
h	Dihydroetorphine	
i	Diphenoxylate	
j	Fentanyl	
k	Isomethadone	
l	Levo-alphacetylmethadol	• Levo-alpha-acetylmethadol • Levomethadyl Acetate • LAAM
m	Levomethorphan	
n	Levorphanol	
o	Metazocine	
p	Methadone	
q	Methadone Intermediate, 4 cyano 2 dimethylamino 4,4 diphenyl butane	

r	Moramide Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid	
s	Pethidine (meperidine).	
t	Pethidine Intermediate A, 4-cyano-1-1 methyl-4-phenylpiperidine	
u	Pethidine Intermediate B, ethyl-4-phenylpiperidine-4-carboxylate	
v	Pethidine Intermediate C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	
w	Phenazocine	
x	Piminodine	
y	Racemethorphan	
z	Racemorphan	
aa	Remifentanil	
bb	Sufentanil	
cc	Tapentadol	

R 338.3118 Schedule 2; stimulants. **Rescinded.**

Rule 18. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances and which has a stimulant effect on the central nervous system is included in schedule 2:

—

Substance	
a	Amphetamine, its salts, optical isomers and salts of its optical isomers
b	Lisdexamfetamine, its salts, optical isomers and salts of its optical isomers
c	Methamphetamine, its salts, isomers and salts of its isomers
d	Phenmetrazine and its salts
e	Methylphenidate and its salts

R 338.3119 Schedule 2; depressants. **Rescinded.**

Rule 19. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers, when the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 2:

(a) Amobarbital.

(b) Glutethimide.

(c) Pentobarbital.

(d) Phencyclidine.

(e) Secobarbital.

(f) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt thereof in combination with itself, one another, or 1 or more other controlled substances.

R 338.3119a Schedule 2; hallucinogenic substances. **Rescinded.**
Rule 19a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of nabilone, including its salts, isomers, and salts of isomers when the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 2.

R 338.3119b Schedule 2; immediate precursors. **Rescinded.**
Rule 19b. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains
any quantity of the following substances:
(a) Immediate precursor to amphetamine and methamphetamine:
Phenylacetone
Some trade or other names:
Phenyl-2-propanone;
P2P;
Benzyl methyl ketone;
Methyl benzyl ketone.
(b) Immediate precursors to phencyclidine (PCP):
(i) 1-phenylcyclohexylamine.
(ii) 1-Piperidinocyclohexanecarbonitrile (PCC).

R 338.3120 Schedule 3; stimulants; depressants; nalorphine. **Rescinded.**
Rule 20. (1) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers whether optical, position, or geometric, and the salts of such isomers, when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 3:

(a) Benzphetamine.
(b) Chlorphentermine.
(c) Clortermine.
(d) Phendimetrazine.

(2) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers whether optical, position, or geometric, and the salts of such isomers, when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 3:

(a) Chlorhexadol.
(b) Embutramide.
(c) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal food, drug, and cosmetic act of 1938, 21 U.S.C.§301 et seq.
(d) Ketamine.
(e) Lysergic acid.

(f) Lysergic acid amide.
(g) Methyprylon.
(h) Perampanel.
(i) Pentazocine.
(j) Sulfondiethylmethane.
(k) Sulfonethylmethane.
(l) Sulfonmethane.
(m) Tiletamine-zolazepam.

(3) A compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or a salt thereof and 1 or more other active medicinal ingredients that are not listed in a schedule is included in schedule 3.

(4) A suppository dosage form which contains amobarbital, secobarbital, pentobarbital, or a salt of any of these drugs and which is approved by the food and drug administration for marketing only as a suppository is included in schedule 3.

(5) A substance that contains any quantity of a derivative of barbituric acid or any salt thereof is included in schedule 3.

(6) Nalorphine is included in schedule 3.

(7) Buprenorphine is included in schedule 3.

R 338.3121 Schedule 3; narcotic drugs. **Rescinded.**

Rule 21. Unless specifically excepted, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof is included in schedule 3:

(a) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit when combined with an equal or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with 1 or more active ingredients in recognized therapeutic amounts.

(c) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(d) Not more than 300 milligrams of ethylmorphine per 100 milliliters and not more than 15 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams and not more than 25 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts, including paregoric.

R 338.3121a Schedule 3; hallucinogenic substances. **Rescinded.**

Rule 21a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States

food and drug administration approved drug product and that has a hallucinogenic effect on the nervous system, including its salts, isomers, and salts of isomers when the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 3.

R 338.3122 Schedule 3; anabolic steroids; exemptions. **Rescinded.**

Rule 22.(1) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of an anabolic steroid, including its salts, isomers, and salts of isomers if the existence of such salts of isomers is possible within the specific chemical designation, is included in schedule 3. As used in this rule, the term "anabolic steroid means any of the following drugs or hormonal substances which are chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, and which promote muscle growth:

Substance	
a	1-Androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene; 3alpha,17beta-dihydroxy-5alphaandrost-1-ene)
b	1-Androstenedione (5alpha-androst-1-en-3,17-dione)
c	3Alpha,17beta-dihydroxy-5alpha-androstane
d	3Beta,17beta-dihydroxy-5alpha-androstane
e	4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene)
f	4-Androstenedione (androst-4-en-3,17-dione)
g	4-Hydroxy-19-nortestosterone (4,17beta-dihydroxyestr-4-en-3-one)
h	4-Hydroxytestosterone (4,17beta-dihydroxyandrost-4-en-3-one)
i	5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene)
j	5-Androstenedione (androst-5-en-3,17-dione)
k	13Beta-ethyl-17beta-hydroxygon-4-en-3-one
l	17Alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane
m	17Alpha-methyl-3beta,17beta-dihydroxy-5alpha-androstane
n	17Alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene
o	17Alpha-methyl-4-hydroxynandrolone (17alpha-methyl-hydroxy-17beta-hydroxyestr-4-en-3-one)
p	17Alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one)
q	19-nor-4, 9(10)-androstadienedione.
r	19-nor-5-androstendedione (estr-5-en-3, 17-dione)
s	Boldenone
t	Bolasterone
u	Boldione
v	Calusterone
w	4-chlortestosterone (clostebol)
x	Dehydrochlormethyltestosterone
y	Desoxymethyltestosterone
z	Drostanolone
aa	Ethylestrenol

~~bb~~	~~Fluoxymesterone~~
~~cc~~	~~Formebolone~~
~~dd~~	~~Mesterolone~~
~~ee~~	~~Methandriol~~
~~ff~~	~~Methandrostenolone (methandienone)~~
~~gg~~	~~Methasterone~~
~~hh~~	~~Methenolone~~
~~ii~~	~~Methyltestosterone~~
~~jj~~	~~Mibolerone~~
~~kk~~	~~Nandrolone~~
~~ll~~	~~Norethandrolone~~
~~mm~~	~~Oxandrolone~~
~~nn~~	~~Oxymesterone~~
~~oo~~	~~Oxymetholone~~
~~pp~~	~~Prostanozol~~
~~qq~~	~~Stanolone (4-dihydrotestosterone)~~
~~rr~~	~~Stanozolol~~
~~ss~~	~~Testolactone~~
~~tt~~	~~Testosterone~~
~~uu~~	~~Trenbolone~~
~~vv~~	~~Any salt, ester, or isomer of a drug or substance described or listed in this subrule, if that salt, ester, or isomer promotes muscle growth.~~

~~(2) An anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the United States drug enforcement administration for such administration is specifically excepted from schedule 3.~~

~~(3) The following anabolic steroid products are exempted from all schedules of controlled substances:~~

~~—~~

~~Substance~~	
~~a~~	~~Esterified estrogens 1.25 milligrams and methyl testosterone 2.5 milligram tablets.~~
~~b~~	~~Esterified estrogens 0.625 milligrams and methyl testosterone 1.25 milligram tablets.~~
~~c~~	~~Conjugated estrogens 1.25 milligrams and methyl testosterone 10 milligram tablets.~~
~~d~~	~~Conjugated estrogens 0.625 milligrams and methyl testosterone 5 milligram tablets.~~
~~e~~	~~Testosterone enanthate 90 milligram/milliliter and estradiol valerate 4 milligram/milliliter injection.~~
~~f~~	~~Testosterone cypionate 50 milligram/milliliter and estradiol cypionate 2 milligram/milliliter injection.~~

~~R 338.3123 Schedule 4; depressants; drugs affecting central nervous system: stimulants; exempt chemical preparations for industrial use; exceptions; narcotic drugs.~~ **Rescinded.**

~~Rule 23. (1) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system, including its salts, isomers, and the salts of isomers when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 4:~~

	~~Substance~~
~~a~~	~~Alfaxalone~~
~~b~~	~~Alprazolam~~
~~c~~	~~Barbital~~
~~d~~	~~Bromazepam~~
~~e~~	~~Camazepan~~
~~f~~	~~Carisoprodol~~
~~g~~	~~Chloralbetaine~~
~~h~~	~~Chloral hydrate~~
~~i~~	~~Chlordiazepoxide~~
~~j~~	~~Clobazam~~
~~k~~	~~Clonazepam~~
~~l~~	~~Clorazepate~~
~~m~~	~~Clotiazepam~~
~~n~~	~~Cloxazolam~~
~~o~~	~~Dichloralphenazone~~
~~p~~	~~Delorazepam~~
~~q~~	~~Dextropropoxyphene~~
~~r~~	~~Diazepam~~
~~s~~	~~Estazolam~~
~~t~~	~~Eszopiclone~~
~~u~~	~~Ethchlorvynol~~
~~v~~	~~Ethinamate~~
~~w~~	~~Ethyl loflazepate~~
~~x~~	~~Fludiazepam~~
~~y~~	~~Flunitrazepam~~
~~z~~	~~Flurazepam~~
~~aa~~	~~Fospropfol~~
~~bb~~	~~Halazepam~~
~~cc~~	~~Haloxazolam~~
~~dd~~	~~Indiplon~~
~~ee~~	~~Ketazolam~~
~~ff~~	~~Loprazolam~~
~~gg~~	~~Lorazepam~~
~~hh~~	~~Lorcaserin~~
~~ii~~	~~Lormetazepam~~
~~jj~~	~~Mebutamate~~
~~kk~~	~~Medazepam~~
~~ll~~	~~Meprobamate~~
~~mm~~	~~Methohexital~~

~~nn~~	~~Methylphenobarbital (mephobarbital)~~
~~oo~~	~~Midazolam~~
~~pp~~	~~Modafinil~~
~~qq~~	~~Nimetazepam~~
~~rr~~	~~Nitrazepam~~
~~ss~~	~~Nordiazepam~~
~~tt~~	~~Oxazepam~~
~~uu~~	~~Oxazolam~~
~~vv~~	~~Paraldehyde~~
~~ww~~	~~Petrichloral~~
~~xx~~	~~Phenobarbital~~
~~yy~~	~~Pinazepam~~
~~zz~~	~~Prazepam~~
~~aaa~~	~~Quazepam~~
~~bbb~~	~~Suvorexant~~
~~ccc~~	~~Temazepam~~
~~ddd~~	~~Tetrazeoam~~
~~eee~~	~~Tramadol~~
~~fff~~	~~Triazolam~~
~~ggg~~	~~Zaleplon~~
~~hhh~~	~~Zolpidem~~
~~iii~~	~~Zopiclone~~

~~(2) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of fenfluramine having a potential for abuse associated with an effect on the central nervous system, including its salts, isomers, whether optical, position, or geometric, and the salts of such isomers when the existence of such salts, isomers, and the salts of isomers is possible, is included in schedule 4.~~

~~(3) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, whether optical, position, or geometric, and the salts of isomers when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 4.~~

~~Substance~~	
~~a~~	~~Cathine ((+)-norpseudoephedrine)~~
~~b~~	~~Dexfenfluramine~~
~~c~~	~~Diethylpropion~~
~~d~~	~~Fencamfamin~~
~~e~~	~~Fenproporex~~
~~f~~	~~Mazindol~~
~~g~~	~~Mefenorex~~
~~h~~	~~Phentermine~~
~~i~~	~~Pemoline, including organometallic complexes and chelates thereof~~

j	Pipradrol
k	Sibutramine
l	SPA((-)-1-dimethylamino-1,2-diphenylethane)

(4) Unless specifically excepted or unless listed in another schedule, any natural compound, mixture, or prescription which contains butorphanol, including its optical isomers and its salts, is included in schedule 4.

(5) Chloral hydrate is designated as an exempt chemical preparation for industrial use when packaged in a sealed, oxygen free environment under nitrogen pressure and safeguarded against exposure to air.

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation containing limited quantities of not more than 1 milligram of difenoxin and not less than 25 micrograms of atrophine sulfate per dosage unit or any salts thereof is included in schedule 4.

R 338.3125 Schedule 5; narcotics added to nonnarcotic compounds. **Rescinded.**

Rule 25. (1) Schedule 5 includes pregabalin and lacosamide by whatever official, common, usual, chemical, or brand name designated.

(2) Schedule 5 includes ezogabine by whatever official, common, usual, chemical, or brand name designated.

(3) Schedule 5 includes gabapentin by whatever official, common, usual, chemical, or brand name designated.

(4) A compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which includes 1 or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation a valuable medicinal quality other than that possessed by the narcotic drug alone, is included in schedule 5:

Substance	
a	Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams, and not more than 10 milligrams per dosage unit.
b	Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams, and not more than 4 milligrams per dosage unit.
c	Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams, and not more than 5 milligrams per dosage unit.
d	Not more than 100 milligrams of opium per 100 milliliters or per 100 grams, and not more than 5 milligrams per dosage unit.
e	Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
f	Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of pyrovalerone which has a stimulate effect on the central nervous system, including its salts, isomers, and salts of isomers, is included in schedule 5.

R 338.3126 Schedule 5; ephedrine; exceptions. **Rescinded.**

~~Rule 26. (1) Except as otherwise provided in subrule (2) of this rule, 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.~~
~~(2) The following are not included in schedule 5:~~
~~(a) A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine if the drug product may lawfully be sold over the counter without a prescription under federal law, is labeled and marketed in a manner consistent with the pertinent over the counter tentative final or final monograph, is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement and if 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, packaged in blister packs with not more than 2 tablets or caplets per blister.~~
~~(ii) An anorectal preparation containing not more than 5% ephedrine.~~
~~(b) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria:~~
~~(i) It contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids provided in applicable regulations adopted by the United States food and drug administration and contains no other controlled substance.~~
~~(ii) It does not contain hydrochloride or sulfate salts of ephedrine alkaloids.~~
~~(iii) It is packaged with a prominent label securely affixed to each package that states all of the following:~~
~~(A) The amount in milligrams of ephedrine in a serving or dosage unit.~~
~~(B) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.~~
~~(C) 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 provided in applicable regulations adopted by the United States food and drug administration.~~
~~(D) That improper use of the product may be hazardous to a person's health.~~

R 338.3127 ~~Exclusions for nonnarcotic substances which are not scheduled.~~ **Rescinded.**
Rule 27. ~~(1) A nonnarcotic substance which, under the federal food, drug, and cosmetic act of 1938, 21 U.S.C. §301 et seq., may be lawfully dispensed without a prescription is excluded from all schedules pursuant to the provisions of section 7208(2) of the act. A substance which contains 1 or more controlled substances in such a proportion or concentration to vitiate the potential for abuse is an excluded substance.~~
~~(2) An excluded substance is a deleterious drug as defined in section 7104(6) of the act and may only be manufactured, distributed, or dispensed by a person who is licensed to manufacture, distribute, or dispense a controlled substance under the act.~~

R 338.3129 ~~Excepted components.~~ **Rescinded.**

~~Rule 29. A compound, mixture, or preparation which contains a depressant or stimulant substance, which is of a similar quantitative composition shown in federal regulations as an excepted compound, or which contains a lesser quantity of a controlled substance or other substances which do not have a stimulant, depressant, or hallucinogenic effect, and which is restricted by law to dispensing by prescription is excepted from the provisions of sections 7212, 7214, 7216, 7218, and 7220 of the act. Compliance with the federal law concerning an excepted compound is deemed compliance with this rule.~~

PART 3. LICENSES

R 338.3131 Rescinded.

R 338.3132 ~~Activities requiring separate licenses~~ **Controlled substance license**.

Rule 32. (1) ~~The following activities are deemed to be independent of each other, shall be conducted under separate licenses, and shall comply with all of the requirements and duties prescribed by law for persons who are licensed to engage in such coincidental activities:~~ **A person who manufactures, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall apply for a controlled substance license by submitting to the department a completed application on a form provided by the department along with the requisite fee and meet both of the following requirements:**

(a) Except for a prescriber in subsection (3)(b)(ii) a separate license is required for each principal place of business or professional practice where the applicant stores, manufactures, distributes, prescribes, or dispenses controlled substances.

(b) An applicant shall obtain a separate controlled substance license for each practitioner license issued under Article 15. The controlled substance license shall be renewed when the Article 15 license is renewed and shall be for an equal number of years.

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, an applicant for licensure shall satisfy all of the following requirements:

(a) An applicant's license shall be verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a controlled substance license. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

(b) An applicant who intends to conduct research involving controlled substances shall submit all of the following:

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

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

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

(c) An applicant who intends to conduct instructional activity involving controlled substances hall submit all of the following information:

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

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

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

(c) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information:

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

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

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

(3) The following activities require a controlled substance license.

(a) _____Manufacturing and distributing a controlled substance **in schedules 2-5**. ~~A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** who is licensed 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**.

(b) _____Dispensing a controlled substance listed in schedules 2 to 5. A ~~physician~~ **prescriber or practitioner 7306(3)** 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**.

(i) A pharmacist shall maintain one controlled substance license from this state in order to may dispense from any licensed pharmacy in this state.

(ii) A prescriber or practitioner who holds a controlled substance license to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations shall not be required to obtain a separate controlled substance license for each physical location of the business or professional practice if the prescriber or practitioner only prescribes at the other locations.

(c) _____Conducting research and instructional activity with a controlled substance listed in schedule 1**.** ~~as follows: (i) A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** who is licensed to conduct research with controlled substances listed in schedule 1 **in this state** may do both of the following:

~~(A)~~ **(i)** Manufacture the substances as set forth in the research protocol that is filed and approved by the ~~federal food and drug administration~~ **FDA** and the ~~drug enforcement administration~~ ~~(~~DEA~~)~~ pursuant to the provisions of 21 ~~C.F.R.§~~**CFR** 1301.18 and submitted **to the department** with the application for licensure. ~~The Code of Federal Regulations, Title 21, Food and Drugs, part 1301, containing §1301.18 is available free of charge via the Internet at web-site http://www.gpoaccess.gov. Printed copies may be purchased by mail order from the United States Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet at web-site http://bookstore.gpo.gov at a cost of $24.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. §1301.18 also are available for inspection and~~

~~for distribution to the public at cost at the~~ **Board of Pharmacy, Bureau of Professional Licensing,** ~~Department of Community Health, Bureau of Health Professions~~ **Licensing and Regulatory Affairs**, ~~Ottawa Building - First Floor, 611 West Ottawa,~~ **P.B. Box 30670,** ~~Lansing, MI 48909.~~

~~(B)~~ **(ii)** Distribute the substances to ~~other~~ ~~persons~~ **others** who are licensed ~~or authorized~~ **by this state** to conduct research or chemical analysis with the schedule 1 substances.

~~(ii) A licensed physician~~ **??prescriber licensed to** _____ ~~who is authorized to conduct research with schedule 1 substances under federal law may~~ **also** ~~conduct research with those substances, upon furnishing the administrator~~ **department** ~~with evidence of that~~ **the** ~~federal authorization. A separate license is not required for the research activity.~~

(d) _____Conducting research with a controlled substance listed in schedules 2 to 5. ~~A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** who is licensed ~~or authorized~~ **by this state** to conduct research with ~~the~~ controlled substances listed in schedules 2 to 5 may **also participate in the following activities:**

(i) ~~conduct~~ **Conduct** chemical analysis with the substances listed in those schedules~~,~~**.**

(ii) ~~manufacture~~ **Manufacture** the substances if, and to the extent that, such manufacture is set forth in a statement filed with the application for licensure **pursuant to subrule (1)(b)**~~,~~ **.**

(iii) ~~distribute~~ **Distribute** the substances to other persons who are licensed ~~or authorized~~ **in this state** to conduct research, chemical analysis, or instructional activity with the substances~~,~~ **.**

(iv) ~~and conduct~~ **Conduct** instructional activities with the substances.

(e) _____Conducting instructional activities with a controlled substance listed in schedules 2 to 5.

~~(f) Prescribing, dispensing, or administering a controlled substance to a drug-dependent person in a drug treatment and rehabilitation program.~~

~~(g)~~ **(f)** _____Conducting chemical analysis with a controlled substance listed in any schedule. ~~A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** who is licensed or authorized to conduct chemical analysis with all controlled substances may manufacture such substances for analytical or instructional purposes, distribute the substances to other persons who are licensed or authorized to conduct chemical analysis, instructional activity or research with the substances, and conduct instructional activities with the substances.

(g) A pharmacy stocking patient medication in an automated device located at a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109. The pharmacy responsible for the device shall obtain an additional controlled substance license for each location.

~~(2)~~ **Except for a prescriber in subsection (5)** ~~A~~ **a** ~~a~~separate license is required for each ~~principal place of business or professional practice~~ **where the applicant stores, manufactures, distributes, prescribes, or dispenses controlled substances**. ~~A principal place of business or a professional practice is the physical location where controlled~~

~~substances are manufactured, grown, cultivated, processed, or by other means produced or prepared, distributed, stored, or dispensed by a licensee.~~

~~(3) If a principal place of business or professional practice consists of multiple locations, then each location shall obtain a separate controlled substance license if controlled substances are received, stored, administered, or dispensed at that location.~~

~~(4) A prescriber or practitioner who holds a controlled substance license to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations shall not be required to obtain a separate controlled substance license for each physical location of the principal place of business or professional practice if the prescriber or practitioner only prescribes at the other locations location .~~

~~(5) A pharmacist **shall maintain one** who holds a controlled substance license **from this state in order to** may dispense from any licensed pharmacy **in this state**.~~

~~(6) A separate controlled substances license is required, as provided in R 338.3154(4), when controlled substances are stored in an automated device and the automated device is not located at the same address as the pharmacy responsible for the device.~~

~~**(7) When patient medication is stocked in an automated device, the pharmacy responsible for the device shall obtain an additional controlled substance license for each hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109.**~~

R 338.3133 Rescinded.

R 338.3134 Rescinded.

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

Rule 35. (1) ~~Pursuant to section 7301 of the act, MCL 333.7301, an~~ **An** individual **who is applying for** ~~seeking~~ a controlled substance license or who is licensed to prescribe or dispense controlled substances **pursuant to section 7303 of the code, MCL 333.7303,** shall complete a 1-time training, ~~offered after promulgation of this rule,~~ in opioids and controlled substances awareness that meets the following standards:

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

(i) Use of opioids and other controlled substances.

(ii) Integration of treatments.

(iii) Alternative treatments for pain management.

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

(v) The stigma of addiction.

(vi) Utilizing the ~~Michigan Automated Prescription System (~~MAPS~~)~~.

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

(viii) Security features **for opioids and other controlled substances and prescriptions,** and proper disposal requirements for ~~prescriptions~~ **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 ~~act~~ **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 ~~act~~ **code, MCL 333.16101 to 333.18838,** for initial licensure or registration, or by a college or university.

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) A prescriber or dispenser shall ~~not~~ delegate**, allow by a practice agreement,** or order the prescribing~~,~~ **or** dispensing~~, or administering~~ of a controlled substance as authorized by ~~this~~ **the** ~~act~~ **code** to ~~an advanced practice registered nurse, registered professional nurse, or licensed practical nurse~~ **an individual, other than a physician's assistant,** ~~unless the nurse complies~~ **only after the individual has complied** with **subrules (1) and (5) of** this rule. **A physician's assistant is subject to subrules (1), (3), and (4) of this rule.**

(3) The department may select and audit licensees and request documentation of proof of completion of training. **A licensee shall maintain proof of completion of training for 5 years.** If audited, an individual shall provide an acceptable proof of completion of training, including either of the following:

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

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

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

(a) A licensee who is renewing his or her controlled substance license shall complete the controlled substance training by the end of ~~The requirements specified in this rule apply to controlled substance license renewals beginning with~~ the first renewal cycle **that begins** after ~~the~~ **January 4, 2019**. ~~promulgation of this rule and for initial licenses issued after September 1, 2019~~.

(b) Other than a license renewal under (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 July 1, 2021, an individual, other than a physician's assistant, who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense

a controlled substance by a prescriber or dispenser as authorized by the code shall complete the controlled substance training required by subrule (1) of this rule.

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

R 338.3136 ~~Information in applications.~~ **Rescinded.**

~~Rule 36. (1) A researcher shall include, in his or her application for licensure, all of the following information:~~

~~(a) His or her credentials to conduct the proposed research.~~

~~(b) The protocol and description of the nature of the proposed research.~~

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

~~(2) A person who conducts instructional activity shall include, with his or her application for licensure, all of the following information:~~

~~(a) His or her 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.~~

~~**(3) A person who conducts chemical analysis involving controlled substances shall include, with his or her application for licensure, all of the following information:**~~

~~**(a) His or her credentials to conduct the proposed chemical analysis.**~~

~~**(b) The protocol and description of the nature of the chemical analysis.**~~

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

R 338.3137 Waiver of license requirement.

Rule 37. (1) The requirement of licensure is waived for the following persons in the circumstances described in this rule:

~~(a) An officer or employee of the drug enforcement administration~~ **DEA** ~~while engaged in the course of official duties.~~

~~(b) An officer of the United States customs service while engaged in the course of official duties.~~

~~(c) An officer or employee of the United States food and drug administration~~ **FDA** ~~while engaged in the course of official duties.~~

~~(d)~~ ~~A federal officer who is lawfully engaged in the enforcement of a federal law relating to controlled substances, drugs, or customs and who is duly authorized to possess controlled substances in the course of that person's official duties.~~

~~(e) An officer or employee of the~~ **this** ~~state of Michigan, or a political subdivision or agency thereof, who is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties.~~

(a) A prescriber, possessing a license issued under section 7303 of the code, MCL 333.7303, who meets all of the following:

(i) A prescriber, who in the course of his or her professional practice, prescribes, dispenses, or administers a controlled substance listed in schedules 2 to 5 to a drug-dependent person for the purpose of maintenance or detoxification treatment.

(ii) A prescriber who is registered with the DEA to provide maintenance or detoxification treatment and who is in compliance with federal law.

~~(2) An official who is exempted from licensure by this rule may, when acting in the course of that person's official duties, possess a controlled substance and may transfer a controlled substance to any other official who is also exempted by this rule and who is acting in the course of that person's official duties.~~

~~(3) An official who is exempted by this rule may procure a controlled substance in the course of a criminal investigation involving the person from whom the substance was procured or in the course of an administrative inspection or investigation.~~

R 338.3138 Rescinded.

R 338.3139 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 ~~determine~~ **confirm** that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Within ~~10~~ **15** days ~~following discovery~~ of **completion of an investigation regarding** a **suspected** theft or **significant** loss of ~~any~~ **a** controlled substance, a licensee shall notify the **department** ~~administrator~~ of the **suspected** theft or **significant** loss **of a controlled substance** ~~by submitting a United States drug enforcement administration~~ **and submit a copy of the DEA** theft and loss report form 106, ~~a copy thereof,~~ or equivalent document, **to the department,** whether or not the controlled substance is subsequently recovered or the responsible party is identified and action is taken against the party, 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 subsection (3) is significant:

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

(b) The specific controlled substances lost.

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

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

(e) Whether the specific controlled substances are likely candidates 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 controlled substance that is listed in schedule 1 ~~of R 338.3111 to R 338.3114a~~ shall be stored in a securely locked, substantially constructed cabinet that is anchored to a wall or the floor.

(2) A controlled substance that is listed in schedules 2, 3, 4, and 5 ~~of R 338.3116 to R 338.3126~~ shall be stored in a securely locked, substantially constructed cabinet, room, or cart. However, in a pharmacy, the controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

~~(3) Parenteral dosage forms which contain amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and which are required by the federal food, drug, and cosmetic act~~ **Federal Food, Drug, and Cosmetic Act** ~~of 1938, 21 U.S.C.§301 et seq., or by regulations promulgated thereunder, to be kept under refrigeration may be stored in compliance with the schedule III regulations set forth in the provisions of 21 C.F.R. §§1301.71 to 1301.76. The Code of Federal Regulations, Title 21, Food and Drugs, part 1301, containing 21 C.F.R.§§1301.71 to 1301.76, is available~~ **at no cost** ~~the Internet at web-site http://www.access.gpo.gov/nara/cfr. Printed copies may be purchased from the United States Government Printing Office, Superintendent of Documents, P.O.Box 371954, Pittsburgh, PA 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet web-site:~~ **at** ~~http://bookstore.gpo.gov at the cost of $20.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. §§1301.71 to 1301.76~~ **Copies** ~~also are available for inspection and for distribution to the public at cost at~~ **ten cents per page from** ~~the~~ **Board of Pharmacy, Bureau of Professional Licensing, Michigan** ~~Department of Consumer and Industry Services~~ **Licensing and Regulatory Affairs**~~, Bureau of Health Services, Ottawa Building - First Floor, 611West Ottawa,~~ **P.O. Box 30670,** ~~Lansing, MI 48909.~~

~~(4) This rule applies to all licensees.~~

R 338.3145 Employees; disqualification.

Rule 45. (1) The following individuals shall not be employed or otherwise utilized, with or without compensation, ~~**in a pharmacy**~~ by a person who is licensed by the ~~administrator~~ **department** pursuant to section 7303 **of the code, MCL 333.7303**~~, 17711,~~ or **section** 17748 of the ~~act~~ **code, MCL 333.17748,** in any manner or capacity that allows the individuals access to controlled substances:

(a) An individual who the licensee knows, or should reasonably know, to be a substance abuser as defined in section 6107 of the ~~act~~ **code, MCL .6107**. 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 in this state or another state for a violation that involves controlled substances.

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

(2) **A licensee** ~~Delegation~~ **shall not delegate,** pursuant to section 16215 of the ~~act~~ **code, MCL 333.16215,** ~~shall not be made by a licensed person~~ to a licensed or unlicensed individual unless the delegation is in compliance with this rule.

PART 5. RECORDS

R 338.3151 Inventories.

Rule 51. (1) A **person licensed to manufacture, distribute, prescribe, or dispense controlled substances** ~~licensee~~ shall **annually** ~~make~~ **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 shall contain a complete and accurate record of all controlled substances in the possession or control of the licensee on the date the inventory is taken as follows:

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

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

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

(4) A licensee shall indicate on the inventory record whether the inventory was taken as of 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. The inventory taken by use of an oral recording device shall be promptly transcribed.

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

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

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

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

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

R 338.3152 ~~Annual and changed inventories.~~ **Rescinded.**

~~Rule 52. (1) Pursuant to the provisions of section 7321 of the act an inventory shall be taken annually of all stocks of controlled substances in the possession or control of the licensee, in accordance with the requirements of R 338.3151.~~

~~(2) On the effective date of a rule by the administrator or DEA adding a controlled substance to a schedule, which substance was not previously listed in any schedule, a licensee who possesses the substance shall take an inventory of all stocks of the substance on hand and incorporate it in the current inventory. Thereafter, the substance shall be included in each inventory taken.~~

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

Rule 53. (1) A licensee shall **following** shall 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**~~. When patient medication is stocked in an automated device, the pharmacy responsible for~~ keep and make available for inspection **within 48 hours** all records for **controlled substances, including invoices, sales receipts, and other acquisition records as follows:**~~, but excluding sales receipts, however a copy of each receipt shall be retained for 90 days.~~

(a) Acquisition records, except for executed DEA 222 order forms, may be **electronic and may be** kept at a central location, ~~subject to the approval of the administrator~~. ~~The approval shall specify the nature of the acquisition records to be kept and the exact location where the acquisition records will be kept.~~ ~~All records shall be readily retrievable within 48 hours.~~

~~(2) A licensee shall maintain acquisition records, which may be electronic, as follows:~~

~~(a)~~ **(b)** Invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 of R 338.3111 to R 338.3119a shall be maintained in a separate file **from invoices and other acquisition records of all controlled substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3125 and**

~~(b) Invoices and other acquisition records of all controlled substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3125 shall be maintained in a separate file or in such form so that~~ the information ~~required is~~ **must be** readily retrievable from the ordinary acquisition records maintained by the dispenser.

(c) Sales receipts shall be retained for 90 days.

~~(3)~~ **(d)** A licensee shall initial or electronically initial the invoice and indicate the date that the controlled substances are received.

~~(4)~~ **(e)** A licensee shall keep a record, which may be electronic, of all controlled substances dispensed by him or her.

~~(5)~~ **(f)** A prescriber shall keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber:

~~(a)~~ **(i)** Name of **the** patient.

~~(b)~~ **(ii)** Name **and strength** of **the controlled** substance ~~and strength~~.

~~(c)~~ **(iii)** Quantity of **the controlled** substance.

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

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

~~(6)~~ **(g)** Except in medical institutions, patients' original prescriptions shall be sequentially numbered and maintained in chronological order as follows:

~~(a)~~ **(i)** A separate file shall be maintained for dispensed substances listed in schedule 2 of R 338.3116 to R 338.3119a.

~~(b)~~ **(ii)** A separate file shall be maintained for dispensed substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3125.

~~(c)~~ **(g)** The original prescription record shall be kept for 5 years **from the last date of dispensing**. After ~~3~~**2** years, an electronic duplicate may be made of the original paper prescription which shall become the original prescription. Upon request of an authorized

agent of the board, a paper copy of the electronic duplicate prescription shall be presented.

~~(7)~~ **(h)** Records of controlled substances distributed to another licensee, shall include all of the following information and be maintained in the appropriate file described in subrule ~~(2)~~ **(b)** of this rule or in a separate record that is available for inspection:

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

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

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

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

(e) A DEA 222 order form shall be used for schedule 2 drugs.

(8) **Except for controlled substance prescriptions pursuant to subsection (6)(c),** ~~Complete~~ controlled substances records shall be maintained or controlled by the licensee for 2 years~~, except for controlled substance prescriptions, which shall be maintained for 5 years from the last date of dispensing. After 3 years, an electronic duplicate may be made of the original paper prescription which shall become the original prescription. Upon request of an authorized agent of the board, a paper copy of the electronic duplicate prescription shall be presented~~.

R 338.3153a Medication orders for patients in medical institutions.

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

(a) The patient's name.

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

(c) The prescriber's signature.

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

(e) The date of the medication order.

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

(a) The oral order of the prescriber is committed to a written or electronic order in the patient chart by a nurse licensed under part 172 of the ~~act~~ **code**, a physician's assistant licensed under part 170 or 175 of the ~~act~~ **code**, or a pharmacist licensed under part 177 of the ~~act~~ **code** 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 time of next visit or within 7 days.

(3) Original orders shall be preserved for a period of 5 years from the date of patient discharge and shall be readily retrievable for any specific time period. After ~~3~~ **2** years, an electronic duplicate of the original order may be made which shall become the original order. If patient records are kept electronically, then a printed copy shall be immediately

available for a current inpatient and within 48 hours upon request of an authorized agent of the board for any patient of the previous 5 years.

R 338.3154 Medication records in medical institutions.

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

(2) Medication records are required for all controlled substances listed in schedules 2, 3, 4, and 5 of R 338.3116 to R 338.3125. At a minimum, these records shall 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.

~~(e) An annual physical inventory and status of any discrepancies between the inventory and the records of acquisition and the dispensing records.~~

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

(a) Medication records for those controlled substances in schedules 2, 3, 4, and 5 of R 338.3116 to R 338.3125 shall be maintained.

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

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

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

(ii) The quantity of the substance.

(iii) The date of delivery.

(iv) The location of the nursing unit.

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

(vi) Name of distributing pharmacist.

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

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

(i) The name of the substance.

(ii) The dose administered.

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

(iv) The name of the patient.

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

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

(4) A controlled substance that is maintained at a nursing unit shall 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.

~~(4)~~ **(5)** If a controlled substance ~~or any medication or device~~ is dispensed from an automated device, then documentation ~~as to the type of equipment, serial numbers, content, policies, procedures, and location within~~ **of** ~~the facility~~ **of all of the following**

shall 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**~~.~~ ~~When patient medication is stocked in an automated device, the pharmacy responsible for the device shall obtain an additional controlled substance license for each hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109, when the pharmacy is not located at the same address as the facility and controlled substances are dispensed from the automated device. The documentation shall include at least all of the following information~~:

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

(b) The ~~Manufacturer~~ **manufacturer,** ~~name~~ **serial number,** and model number **of the automated device**.

(c) The location of the automated device.

(d) The contents of the automated device.

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

(i) Use of monitors that alert the user when the wrong medication is filled or removed ~~and~~ 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.

~~(d)~~ **(f) The** ~~Policy~~ **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 compliance with federal and state regulations.**

(iii) Accuracy.

(iv) Patient confidentiality.

(v) Access.

(vi) **Type of** ~~Controlled~~ **controlled** substances.

(vii) Data retention or archival.

(viii) Definitions.

(ix) Downtime procedures.

(x) Emergency procedures.

(xi) ~~Inspection~~ **Operator inspections.**

(xii) Installation requirements.

(xiii) Maintenance.

(xiv) Medication security.

~~(xv) Quality assurance.~~

(xvi) Medication inventory.

(xvii) Staff education and training.

(xviii) System set-up and malfunction.

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

(xx) The use of the automated device that includes a requirement that a pharmacist review a prescription or medication order before system profiling or removal of any medication from the automated device for immediate patient administration except in the following situations:

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

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

(C) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.

(D) In each of the situations specified in this paragraph, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.

~~(5) Automated devices shall have adequate security systems and procedures, evidenced by written pharmacy policies and procedures that document all of the following information: Prevention of unauthorized access or use. Compliance with any applicable federal and state regulations. Maintenance of patient confidentiality.~~

(6) ~~Records and electronic data kept~~ **The automated device shall maintain transaction data that includes all** ~~by automated devices shall meet all of the following requirements:~~

~~(a) All events involving~~ **activity regarding** access to the contents of the automated **device** ~~devices shall be recorded electronically~~.

~~(b)~~ **(7) The pharmacy responsible for the automated device shall maintain records related to access to the automated device. The records must** ~~Records shall be maintained by the pharmacy responsible for the device and shall~~ be readily retrievable~~.~~ ~~The records~~ **and** shall include all of the following information:

~~(i)~~ **(a)** The unique identity of **the** device ~~accessed~~.

~~(ii)~~ **(b)** Identification of the individual accessing the **automated** device.

~~(iii)~~ **(c)** The type of transaction.

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

~~(v)~~ **(e)** The name of the patient ~~for whom the drug was ordered~~.

~~(vi)~~ **(f)** ~~Identification~~ **The name and license number** of the pharmacist checking for the accuracy of the medications to be stocked or restocked in the **automated** device.

~~(vii) If the pharmacist delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that is in compliance with R 338.490. This subdivision takes effect April 11, 2003.~~

~~(viii)~~ **(g) Any other** ~~Additional~~ information ~~as~~ the pharmacist ~~may deem~~ **deems** necessary.

(h) For medication removed from the automated device for on-site patient administration, the automated device shall 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 person removing the drug.

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

(8) If the pharmacist delegates the stocking of the automated device, then technologies shall 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.

~~(7) For medication removed from the system for on-site patient administration, the system shall document all of the following information:~~

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

~~(b) The date and time medication was removed from the device.~~

~~(c) The name, initials, or other unique identifier of the person removing the drug.~~

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

~~(8)~~ **(9)** The automated device shall provide a mechanism for securing and accounting for medications once removed from and subsequently returned to, the automated device return bin. Neither medication nor a device may be returned directly to the ~~system~~ **automated device** for immediate reissue or reuse. Medication or devices ~~once~~ removed **from the automated device** shall not be reused or reissued, except as indicated in R 338.486(7).

~~(9)~~ **(10)** The automated device shall provide a mechanism for securing and accounting for wasted or discarded medications.

~~(10) The internal quality assurance documentation for the use and performance of the automated device shall include at least all of the following:~~

~~(a) Safety monitors that include wrong medications removed and administered to patient.~~

~~(b) Accuracy monitors that include filling errors and wrong medications removed.~~

~~(c) Security monitors that include unauthorized access, patients not in the system, system security breaches, and controlled substance audits.~~

~~(d) Policies that establish corrective measures taken to address the problems and errors identified in the internal quality assurance program and its integration to the overall quality assurance policies.~~

~~(11) Policy and procedures for the use of the automated device shall include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:~~

~~(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(i).~~

~~(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).~~

~~(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.~~

~~(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.~~

~~(12) A copy of all pharmacy policies and procedures related to the use of an automated device shall be maintained at the pharmacy responsible for the device's specific location and be available for review by an agent of the board.~~

~~(13) A controlled substance that is maintained at a nursing unit shall 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.~~

~~(14) Records and documents required under this rule shall be maintained or controlled by the pharmacy responsible for the device for 2 years.~~

~~(15)~~ **(11)** 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 shall be dated**,** and signed **by the prescriber,** when issued**,** and shall 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 ~~drug enforcement administration (dea)~~ **DEA** registration number, **preprinted, stamped, typed, or manually** printed name, address, **telephone number or pager number,** and professional designation.

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

(d) The quantity prescribed. For a prescription received in writing, the prescription shall contain the quantity in both written and numerical terms. A written prescription is in compliance if it contains preprinted numbers representative of the quantity next to which is a box or line the prescriber may check.

(e) The directions for use.

(f) In addition, if the prescription is for an animal, then the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance in schedules 2 to 5 shall be written legibly with ink or an indelible pencil~~,~~ or prepared using a printer and shall be signed by the prescriber.

(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, but, pursuant to the ~~act~~ **code**, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the ~~act~~ **code**.

(4) If the controlled substance prescription or order in a medical institution is issued pursuant to delegation under R 338.2304, R 338.2305, R 338.108a, or R 338.108b then the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee shall be on the written prescription. In medical facilities, orders shall contain the signatures of the delegatee and the printed name of the delegating prescriber.

(5) A prescription shall not be issued by a prescriber to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.

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

Rule 61a. (1) A bona fide prescriber-patient relationship is required before a licensed prescriber may prescribe a controlled substance listed in schedules 2 to 5.

~~(2) As used in section 7303a of the act, MCL 333.7303a, a "bona fide prescriber-patient relationship" means a treatment or counseling relationship between a prescriber and a patient in which both of the following are present:~~

~~(a) The prescriber has reviewed the patient's relevant medical or clinical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant medical evaluation of the patient conducted in person or through telehealth. "Telehealth" means that term as defined in section 16283 of the act, MCL 333.16283.~~

~~(b) The prescriber has created and maintained records of the patient's condition in accordance with medically accepted standards.~~

~~(3)~~ **(2)** Pursuant to Section 16204e of the ~~act~~ **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 ~~act~~ **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 ~~act~~ **code**, reviews the patient's relevant medical or clinical records, medical history, and any change in medical condition, and provides documentation in the patient's medical record in accordance 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, ~~hospice patient,~~ or nursing care facility resident and provides documentation in the patient's medical record in accordance with medically accepted standards of care.

(c) The prescriber is prescribing for a patient that has been admitted to a licensed nursing care facility ~~or a hospice,~~ completes the tasks identified in subrule (2)(a) and (2)(b) of this rule in compliance with R 325.20602 or R 325.13302, as applicable, and provides documentation in the patient's medical record in accordance with medically accepted standards of care.

(d) The prescriber is prescribing for a patient for whom the tasks listed in subrule (2)(a) and (2)(b) of this rule have been performed by an individual licensed under article

15 of the ~~act~~ **code**, and the prescriber provides documentation in the patient's medical record in accordance with medically accepted standards of care.

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

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

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

(2) A pharmacist shall require positive identification of individuals to whom controlled substances are dispensed or delivered when the individual is not known to the pharmacist or pharmacy employees. The following provide for waiver of this requirement:

(a) When positive identification is not available and a pharmacist, who in exercising his or her professional judgment, determines that a delay in dispensing the controlled substance may be detrimental to a patient.

(b) Subdivision (a) of this subrule does not exempt a pharmacist from the requirement to submit a patient identifier to **the electronic system for monitoring controlled substances**~~, as defined in R 338.3102(1)(f)~~.

(3) The dispensing pharmacist and pharmacy are responsible for compliance with this rule.

(4) ~~Except as provided by R 338.3162a, a~~ **A** pharmacist may dispense a controlled substance which is listed in schedules 3 to 5 and which is a prescription drug pursuant to the provisions of the ~~federal food, drug, and cosmetic act~~ **Federal Food, Drug, and Cosmetic Act** of 1991, 21 ~~U.S.C. §201.100(b)(i) et seq.~~ **USC 353**, only pursuant to a **prescription on a prescription form, an oral prescription of a practitioner, or a prescription that is electronically transmitted pursuant to R 338.3162a** ~~written, electronically transmitted, or oral order of a prescriber~~ **and** that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained pursuant to an oral order.

(5) If an oral order for a controlled substance listed in schedule 3 to 5 is transmitted by the prescriber's agent under delegation then all of the following shall be recorded on the prescription generated at the pharmacy: The information required by R 338.3161.The transmitting agent's identity. The individual who received the prescription at the pharmacy.

(6) Only an order 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 ~~prescriptions~~ **prescription**; **waiver of electronic transmission**~~"electronically transmitted prescription drug order" defined~~.

Rule 62a. ~~(1) As used in this rule, "electronically transmitted prescription drug order" means a prescription drug order that is communicated from the prescriber directly to the pharmacy by electronic means, so that the data cannot be altered, modified, extracted, viewed, or manipulated in the transmission process.~~

~~(2)~~ **(1) Until October 1, 2021, or the date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, whichever is later, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription if all of the following conditions are satisfied:**

(a) The ~~An electronically transmitted~~ prescription ~~order shall be~~ **is** transmitted to the pharmacy of the patient's choice and ~~shall occur~~ **occurs** only at the option of the patient.

~~(3) A pharmacist may dispense an electronically transmitted prescription drug order only if both of the following conditions are satisfied:~~

~~(a)~~**(b)** The electronically transmitted prescription ~~drug order~~ includes all of the following information:

(i) The name and address of the prescriber.

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

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

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

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

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

~~(vi)~~**(vii)** All other information that is required to be contained in a prescription under ~~the provisions of~~ R 338.3161.

~~(b)~~ **(c)** The pharmacist exercises professional judgment regarding the accuracy or authenticity of the transmitted prescription. Technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement.

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

~~(4)~~ **(2)** An electronically transmitted prescription ~~drug order~~ that meets the requirements of subrule ~~(3)~~ **(1)** of this rule shall be deemed to be the original prescription.

~~(5)~~ **(3)** This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions.

(4) Effective October 1, 2021, or the date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, whichever occurs later,~~An~~ prescribers shall electronically transmit a prescription for a controlled substance consistent with the following requirements:

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

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

(5) An applicant applying for a waiver from section 17754a if the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and shall satisfy all of the following requirements:

(a) The applicant is unable to meet the requirements of section 17754a (1) and (2) of the code, MCL 333.17754a.

(b) The applicant meets one of the following:

(i) The applicant provides evidence satisfactory to the department that he or she has received a waiver of the Medicare requirements for the electronic transmission of controlled substances prescriptions from the federal Centers for Medicare and Medicaid Services.

(ii) The prescriber and dispensing pharmacy are the same entity.

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

(iv) The applicant demonstrates exceptional circumstances.

(6) A waiver is valid for two years and is renewable 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~~ **a** pharmacist, dispensing prescriber, and veterinarian licensed under ~~Part~~ **part** 177 **of the code, MCL 333.17701 to 333.17780,** who dispenses a prescription drug ~~which~~ **that** is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a schedules 2 to 5 controlled substance ~~prescription~~ dispensed:

(a) The patient identifier **identification number**~~, as defined in R 338.3102(1)(f)~~. **For purposes of this subdivision, all of** ~~The~~ **the** following apply:

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

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

(iii) If the **medication being dispensed is for** ~~patient is~~ an animal, **the patient identification number applies to** ~~positive identification of~~ the **individual requesting treatment for the animal** ~~animal's owner~~ **(client)** that meets the requirements of R 338.3102(1)(f)(iv).

(b) ~~The name of the controlled substance dispensed.~~ **The patient's or 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.

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

~~(d)~~ **(i)** The ~~national drug code number (ndc)~~ **NDC** of the controlled substance dispensed.

~~(e)~~ **(j)** The date of issue of the prescription.

~~(f)~~ **(k)** The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

~~(h)~~ **(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.

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

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

~~(i)~~ **(t)** The ~~(dea)~~ **DEA** registration number of the prescriber and the dispensing pharmacy.

~~**(u) If the medication being dispensed is for an animal, positive identification means the animal's description and identification of the individual requesting treatment for the animal, that meets the requirements of subdivision (f)(i) to (iv).**~~

~~(j) The Michigan license number of 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 client** is correct.

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

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 which 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 shall be transmitted in the format established by the ~~american society for automation in pharmacy (asap)~~ **ASAP** telecommunications format for controlled substances.

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

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if he or she demonstrates an inability to report as required by R 338.3162b and he or she agrees in writing to report the data to the department or the department's contractor by submitting a completed maps claim form as defined in R 338.3102(c) or transmitting data via an internet web portal that is provided by the ~~Department~~ **department** or the ~~Department's~~ **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 schedules 2 to 5 controlled substances dispensed.

(2) The data required by R 338.3162b shall be forwarded by on-line transmission, computer diskette, compact disk, or other approved medium, as specified in R 338.3162c to the department or the department's contractor, ~~twice~~ **bi-** ~~monthly and shall include the data for all controlled substances dispensed since the previous transmission or report. Beginning 180 days after these amendatory rules take effect, the data required by R 338.3162b shall be forwarded to the department or the department's contractor~~ by the end of the next business day and shall include the data for all controlled substances dispensed since the previous transmission or report.

(3) For each pharmacist, pharmacy, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, the information shall be mailed or delivered 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 shall include the data for all controlled substances dispensed since the previous transmission or report.

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

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as required, ~~beginning on the date that these amendatory rules take effect,~~ shall be subject to the penalty provisions in section 16221, 17741, or 17768 in article 15 of the ~~act~~ **code**.

R 338.3162e ~~Exemption from reporting requirements~~. **Rescinded.**

~~Rule 62e. A pharmacist, dispensing prescriber, or veterinarian shall be exempt from the reporting requirements under the following circumstances:~~

~~(a) When a controlled substance in schedules 2 to 5 is administered directly to a patient.~~

~~(b) When a controlled substance in schedules 2 to 5 is dispensed from a health facility or agency licensed under article 17 of the act by a dispensing prescriber in a quantity adequate to treat a patient for not more than 48 hours.~~

~~(c) When a veterinary hospital or clinic administers the controlled substance to an animal that is in staying in the veterinary hospital or clinic.~~

R 338.3163 Drug-dependent person; prescribing, dispensing, and administering controlled substance.

Rule 63. (1) A **licensee** ~~prescription~~ shall not ~~be issued~~ **prescribe, dispense, or administer** ~~for~~ a controlled substance ~~nor shall a controlled substance be dispensed or administered~~ to a drug-dependent person for the purpose of continuing his or her drug dependency, except as follows:

(a) A prescriber, licensed in accordance with federal ~~and state~~ law to conduct the drug treatment of a drug-dependent person ~~in a program~~ may **within her or her scope of practice** prescribe, **dispense, and administer** a controlled substance for the purpose of

legitimate treatment of the drug-dependent person. **A prescription may only be written for a schedule 3 through 5 drug.**

(b) A **licensed health professional within the scope of his or her practice may administer or dispense** controlled substance ~~may be administered or dispensed, or both, by a dispenser,~~ directly to a drug-dependent person for the purpose of continuing his or her dependence ~~who is enrolled in a drug treatment and rehabilitation program.~~ **consistent with both of the following requirements:**

(i) The drug-dependent person shall be in one of the following situations:

(A) The drug-dependent person is participating in a drug treatment and rehabilitation program.

(B) The drug-dependent person is experiencing acute withdrawal symptoms and administration of a controlled substance is necessary while the licensed health professional is arranging referral for treatment.

(ii) Not more than one day's supply of medication may be administered or directly dispensed to the drug-dependent person. Such emergency treatment may be carried out for not more than three consecutive days and may not be renewed or extended.

(iii) The controlled substance must be approved by the FDA specifically for use in maintenance or detoxification treatment.

(~~2~~**c**) A **licensed health professional within the scope of his or her practice** ~~controlled substance~~ may ~~be prescribed~~ **administer** ~~or dispensed~~ **a controlled substance** ~~in an acute care hospital to continue maintenance treatment for drug dependency for a patient whose hospitalization is for treatment of a medical condition other than addiction. The enrollment of the patient in an approved maintenance treatment program shall be verified.~~ **to a drug-dependent person consistent with both of the following:**

(i) The licensed health professional is administering a controlled substance to continue maintenance or detoxification treatment as an adjunct to medical or surgical treatment of conditions other than addiction.

(ii) The licensed health professional is administering a controlled substance to relieve intractable pain in which no relief or cure is possible, or none has been found after reasonable efforts.

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 case of an emergency in which all of the following conditions are met:

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

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

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

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

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

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information that is required to be contained in a prescription under provisions of R 338.3161, except for the prescriber's signature.

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

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

Rule 65. Within 7 days after authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall reduce the prescription to writing and have recorded on the prescription's face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription shall be delivered to the pharmacist in person or by mail within 7 days after the oral prescription is issued. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral order which earlier had been reduced to writing. The pharmacist shall notify the department ~~of consumer and industry services~~ if the prescriber fails to deliver a written prescription to him or her. The failure of a pharmacist to notify the department if the prescriber fails to deliver a written prescription voids the authority conferred by this rule to dispense without a written prescription of a prescriber.

R 338.3166 Partial dispensing of schedule 2 substances.

Rule 66. (1) A pharmacist may partially dispense a controlled substance listed in schedule 2 if he or she is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remainder of the prescription may be dispensed within 72 hours after the first partial dispensing. If the remainder of the prescription is not or cannot be dispensed within the 72 hours, the pharmacist shall so notify the prescriber. A further quantity shall not be dispensed beyond the 72 hours without a new prescription.

(2) Prescriptions for schedule 2 controlled substances that are written for a patient in long-term care facilities or for a patient with a medical diagnosis that documents a terminal illness may be filled in partial quantities, including individual dosage units. 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:

(a) Date of the partial filling.

(b) Quantity dispensed.

(c) Remaining quantity authorized to be dispensed.

(d) Identification of the dispensing pharmacist. The total quantity of schedule 2 controlled substances dispensed in all partial fillings shall not be more than the total quantity prescribed. Schedule 2 prescriptions for a patient in a long-term care facility or for a patient with a medical diagnosis that documents a terminal illness shall be valid for a period of not more than 60 days from the issue date unless terminated at an earlier date by the discontinuance of medication. A pharmacist shall record on the prescription whether the patient is terminally ill or is a long-term care facility patient.

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 which is not a prescription medication as determined under the ~~federal food, drug, and cosmetic act~~**Federal, Food, Drug, and Cosmetic Act**, 21 ~~U.S.C. §§~~**USC** 301 to 392, if all of the following provisions are met:

(a) The dispensing pharmacist has determined ~~it~~ **the controlled substance** is to be used for a medical purpose.

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

(c) The purchaser is at least 18 years of age.

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

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

(3) The pharmacist shall maintain a record of the dispensing **without a prescription** of controlled substances listed in schedule 5. The record shall be immediately retrievable and may be maintained in the same manner as required for schedule 5 prescription medication. The record shall contain all of the following information:

(a) The name and address of the patient.

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

(c) The name and quantity of substance purchased.

(d) The date purchased.

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

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

R 338.3168 Refilling of prescriptions.

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

(2) A prescription for a controlled substance listed in schedules ~~3and~~ **3 and** 4 shall not be refilled more than 6 months after the prescription's date of issuance and shall not be refilled more than 5 times. Renewal of the prescription shall be effected and recorded in the same manner as an original prescription.

(3) A partial filling of a controlled substance prescription in schedules 3, 4, and 5 is permissible if all of the following provisions are met:

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

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

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

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

R 338.3169 Rescinded.

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of his or her professional practice ~~only,~~ may dispense**,** ~~or~~ administer~~, or both~~, **or delegate under direct supervision the administering of** a controlled substance listed in schedules 2 to 5 ~~or he or she may cause them to be administered by an assistant under personal charge supervision~~.

~~(2) A prescriber may dispense or administer, or both, in the course of professional practice, a controlled substance listed in schedules 2 to 5, directly to a drug-dependent person for the purpose of continuing the dependence in a drug treatment and rehabilitation program, if the prescriber is appropriately registered under federal law and licensed under state law to treat a drug-dependent person with controlled substances.~~

~~(3)~~ **(2)** A veterinarian, in the course of professional practice ~~only~~ and not for use by a human being, may dispense**,** ~~or~~ administer~~, or both,~~ **or delegate under direct supervision the administering of** a controlled substance listed in schedules 2 to 5 ~~or may cause them to be administered by an assistant or orderly under his or her direction and personal charge supervision~~.

PART 7. DISTRIBUTIONS

R 338.3181 Distributions by dispensers.

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

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

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

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

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

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

Is this another exception to the definition of wholesale distributor?

R 338.3182 Distribution of aqueous and oleaginous solutions. **Rescind.**

~~Rule 82. (1) A pharmacist who is licensed to dispense may distribute, without being licensed to distribute, to a licensed practitioner, an aqueous or oleaginous solution, in a quantity of not more than 1 ounce at any one time, which contains a narcotic controlled substance in a proportion that is not more than 20% of the complete solution and which is to be used by the practitioner in the course of his or her professional practice for administration to a patient. The pharmacist shall maintain a written record that contains all of the following information:~~
~~(a) The date of the transaction.~~
~~(b) The name, form, and quantity of the substance.~~
~~(c) The name, address, and license number of the pharmacist or other licensed person.~~
~~(d) The name, address, and license number of the practitioner.~~
~~(2) In the case of a controlled substance listed in schedules 1 or 2, an order form shall be used and maintained as the written record of the transaction.~~

R 338.3183 Distribution to suppliers.

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

(a) The date of the transaction.

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

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

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

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

R 338.3185 Discontinuances and transfers.

Rule 85. A licensee who wants to discontinue or transfer business activities or a professional practice altogether or only with respect to controlled substances shall return his or her DEA registration and any unexecuted order forms in his or her possession to the ~~drug enforcement administration~~ **DEA**. The **licensee** ~~administrator's license~~ shall ~~be returned~~ **return the state controlled substances license** to the ~~administrator~~ **department**. The transfer of **the** controlled substances is subject to approval by the ~~drug enforcement administration~~ **DEA** or ~~administrator~~ **the department** in accordance with the provisions of 21 C.F.R. S300.

R 338.3186 Use of order forms and invoices.

Rule 86. An order form shall be used to distribute schedule 2 substances and an invoice shall be used to distribute schedules 3 to 5 substances. The order form may be executed only by a practitioner who is licensed to prescribe or dispense controlled substances.

PART 8. ADMINISTRATIVE AND DISCIPLINARY PROCEDURE

R 338.3191 - 338.3198a Rescinded.

R 338.3199 - 338.3199q Rescinded.