MICHIGAN BOARD OF PHARMACY
FEBRUARY 15, 2023, MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on February 15, 2023, at 611 West Ottawa Street, Upper-Level Conference Room 3, Lansing, Michigan 48933.

CALL TO ORDER

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

ROLL CALL

Members Present: Grace Sesi, PharmD, Chairperson
Michael Sleiman, PharmD, Vice Chairperson
Keith Binion, BS, C.Ph.T.
Pierre Boutros, R.Ph. (out 12:04 a.m. to 12:10 p.m.)
Rony Foumia, R.Ph.
David Hills, Public Member
Kelli Oldham, Public Member
Sandra Taylor, R.Ph.
Maria Young, R.Ph.

Members Absent: Kyle McCree, Public Member

Staff Present: Andria Ditschman, Departmental Specialist,
Boards and Committees Section
Andrew Hudson, Manager, Pharmacy & Drug Monitoring Section
Dena Marks, Departmental Specialist, Boards and Committees Section
Jacob Poynter, Manager, Licensing Division
Michele Wagner-Gutkowski, Assistant Attorney General
Stephanie Wysack, Board Support Technician
Boards and Committees Section

APPROVAL OF AGENDA

MOTION by Foumia, seconded by Oldham, to approve the Amended Agenda, as presented.

A voice vote followed.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Oldham, seconded by McCree, to approve the December 7, 2022, meeting minutes as written.

A voice vote followed.

MOTION PREVAILED

HPRP Annual Report

Marks provided an overview of the HPRP program and presented the HPRP Executive Summary: October 1, 2021, through September 30, 2022.

Pharmacy Inspection Presentation

Hudson provided a presentation titled “Pharmacy Inspections; Common Violations” (Attachment 1).

REGULATORY CONSIDERATONS

None

OLD BUSINESS

None

NEW BUSINESS

Waiver of 10 Mile Limitation on Remote Pharmacy

Forest Community Pharmacy

MOTION by Taylor, seconded by Hills, to grant the Waiver of 10 Mile Limitation.

Discussion was held.

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

MOTION PREVAILED

Pharmacy Technician Training Program and Examination

Corewell Health William Beaumont University Hospital

Taylor recused herself.

MOTION by Boutros, seconded by Oldham, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Boutros, seconded by Sleiman, to approve the pharmacy technician examination.

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

MOTION PREVAILED

Purpose Healthcare Training Center

MOTION by Binion, seconded by Young, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Young, seconded by Taylor, to table the matter, requesting a copy of the curriculum/syllabus.

A voice vote followed.

MOTION PREVAILED

Internship Hour Approval Request

MOTION by Foumia, seconded by Taylor, to approve the Internship Hour Approval Request for 2300 hours.

Discussion was held.

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

MOTION PREVAILED

Continuing Education

Foumia directed the board to the list of continuing education programs for consideration (Attachment 2).

MOTION by Oldham, seconded by Sleiman, to approve the continuing education list as presented.

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

MOTION PREVAILED

Rules Discussion

Central Fill Pharmacies – Public Comments

Ditschman stated that only a few public comments were received during the open comment period. Ditschman provided an overview of the Rules Committee's recommendations that were incorporated into the draft (Attachment 3).

MOTION by Sleiman, seconded by Oldham, to approve the draft as presented.

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

MOTION PREVAILED

Program for Utilization of Unused Drugs

MOTION by Taylor, seconded by Hills, to discuss.

A voice vote followed.

MOTION PREVAILED

Ditschman presented the draft rules (Attachment 4).

Discussion was held.

MOTION by Boutros, seconded by Foumia, to approve the draft rules as presented.

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

MOTION PREVAILED

Pharmacy – Controlled Substances

Ditschman provided an overview of substantive changes made to the draft rules (Attachment 5).

MOTION by Young, seconded by Boutros, to discuss.

A voice vote followed.

MOTION PREVAILED

Discussion held.

MOTION by Sleiman, seconded by Foumia, to approve the draft rules as presented, and modified as follows:

R 338.3162b (1)(s) to read “The patient’s or client’s location code when receiving the dispensed controlled substance, as specified by ASAP.”

R 338.3163: Removing only parts of the rule that were inconsistent or stricter than the MAT Act.

R 338.3111: Scheduling/not scheduling of Brorphine, Synthetic Cannabinoids, Synthetic Cathinones, Gabapentin, Hydrocodone-containing products (HCPs), Hydrocodone and Dihydrocodeine-Sch2, Isomers, Marihuana, Pentazocine, Phencyclidine-Sch 2 Analogs-Sch 1 (PCP), Salvia divinorum and Salvinorin A, and Tetrahydrocannabinols, as discussed.

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

MOTION PREVAILED

Chair Report

Sesi stated that she would be attending the NABP Annual Conference, May 10 – 12, 2023 in Tennessee as well as Young, Binion, Sleiman and possibly Foumia. Sleiman will serve as the board's delegate.

Department Update

Ditschman stated that the SpotRx Pilot Program had ended due to the closing of the pharmacy, effective February 8, 2023.

Ditschman stated that equipment has been installed in the meeting rooms for recording of board meetings, effective March 28, 2023. She stated that the board will need to be mindful of microphones and to make sure to speak loudly and clearly.

Ditschman stated that the bureau will hold the next Board Member Training on March 8, 2023, at 1:00 p.m. via Zoom. All board members are welcome to attend.

Wysack stated that members who are eligible for reappointment should submit their application soon. The application is located online at www.michigan.gov/whitmer under Appointments in the drop-down menu.

Wysack reminded board members to check their state emails on a regular basis. She stated that notification of attendance and possible recusal is important in determining quorum.

PUBLIC COMMENT

None

ANNOUNCEMENTS

The next regularly scheduled meeting will be held April 19, 2023, at 10:00 a.m. at the Ottawa Building, 611 West Ottawa Street, Upper-Level Conference Center Room 3, Lansing, Michigan 48933.

ADJOURNMENT

MOTION by Boutros, seconded by Sleiman, to adjourn the meeting at 12:30 p.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on April 19, 2023.

Prepared by:
Stephanie Wysack, Board Support Technician February 16, 2023
Bureau of Professional Licensing

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Pharmacy Inspections: Common Violations

February 15, 2023

Presented by:
Andrew Hudson, Administrative Manager
Janice Waldmiller, R.Ph. Pharmacy Specialist
Pharmacy and Drug Monitoring Section
Bureau of Professional Licensing

Speaker Introduction
Andrew Hudson and Janice Waldmiller

Andrew Hudson served as an assistant attorney general from 2013 through 2017 and was assigned to litigate cases on behalf of the newly-formed Drug Monitoring Section to address drug diversion and overprescribing by health professionals. In July 2017, Mr. Hudson became administrative manager of DMS.

After graduating from Ferris State University College of Pharmacy in 1995, Janice Waldmiller worked in the retail practice setting of pharmacy. Ms. Waldmiller began working for the State of Michigan as a Pharmacy Specialist in 2010. Ms. Waldmiller's current responsibilities are conducting inspections of multiple practice settings, conducting investigations and analyzing MAPS data.

Introduction

Pharmacy & Drug Monitoring Section

- Field staff consists of 6 pharmacy specialists and 5 regulation agents
- Responsibilities include but are not limited to:
  - Investigations - on behalf of several boards (Pharmacy, Medicine, Osteopathic Medicine, Physician Assistants, and Nursing, Dentistry, and Veterinary Medicine)
    - Drug diversion
    - Overprescribing of controlled substances
    - Overdispensing of controlled substances
    - Substandard practice of pharmacy (ex. health care fraud, dispensing errors)
  - Inspections

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Inspections

- DMS personnel conduct pre-licensure inspections for all in-state pharmacy and wholesaler applicants (pre-licensure) and relocations
- Random inspections of operational retail and long-term care pharmacies are conducted monthly on a county-by-county basis.
- Animal shelter applicants or relocation applicants are site-inspected when applying for licenses to use drugs for euthanasia or sedation
- Physicians who possess a drug control license are inspected on a case-by-case basis.
- Research and analytical lab applicants are inspected as appropriate on a case-by-case basis
- During an authorized investigations, inspections are routinely performed, particularly if the allegation relates to inappropriate dispensing or fraud.
- Disciplinary monitoring inspections of licensees on probation are conducted as dictated by Board order.

Other Entities Who Conduct Inspections

- Sterile compounders must obtain a Board-approved accreditation (always includes an inspection)

- FDA conducts some inspections of pharmacies
  - FDA may notify the Bureau, who may participate or observe these inspections

- Insurance Companies and PBMs – Department notified of the results if the inspection uncovers…
  - Fraud, Waste, and Abuse
  - Concerns with controlled substance storage and potential diversion

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Regulations and Rules

- Michigan Public Health Code (MCL) – statutes (laws)
- Article 15 of Public Health Code – covers General Provisions for all Health Professions
- Article 7 of Public Health Code – covers controlled substances
- Administrative Rules for the Board of Pharmacy – rules clarifying statute

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Common Inspection Violations

- Licenses Displayed and Individuals Licensed
  - MCL 333.16191(2) - licenses shall be displayed “prominently and where visible to the public”
  - MCL 333.17739(2) Technicians must be licensed.
  - MCL 333.17739a(3) – A pharmacist shall not allow an unlicensed individual to work as a technician; note that this applies to any pharmacist, not just the PIC.

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Common Inspection Violations

- Pharmacist-in-Charge
  - MCL 333.17748(4) Change in PIC not reported to Department within 30 days
    - This can be done directly by logging into MiPlus Account, no paper changes.
    - Can also send email to bplhelp@Michigan.gov
    - Displayed on LARA Public Website

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Common Inspection Violations

- Quality and Purity of medications
  - R 338.589(1) A Pharmacist has the professional responsibility for the strength, quality, purity and labeling of all drugs…
    - Lack of temperature monitoring
    - Expired medications
    - Unlabeled and incorrectly labeled medications in general stock

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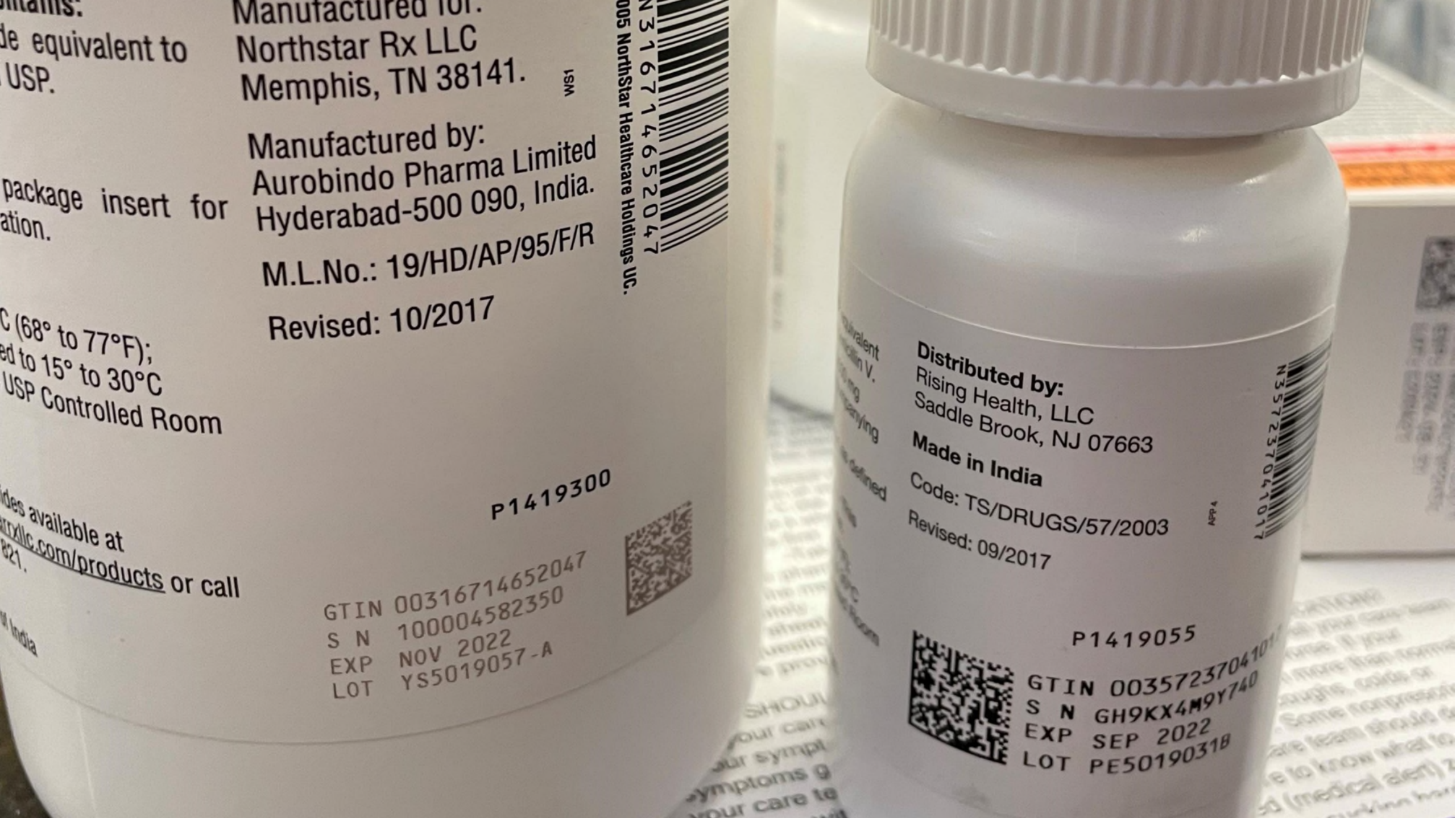
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TURN TIGHTLY
30
PULVULES
PROZAC
FLUOXETINE
CAPSULES, USP
20 mg
Dispense in a tight, light-resistant container
Keep Tightly Closed
GTIN: 00307775105308
Exp. Date/Control No./Serial No.
0777-3105-30

Common Inspection Violations

- Quality and Purity of medications
  - R 338.585 Custom Patient Medication Packages (CPMP) - a package which is prepared by a pharmacist for a specific patient and which contains 2 or more prescribed solid oral dosage forms.
    - (2)(a)(i) - serial number must be recorded on labels.
    - (2)(a)(vi) - 60-day expiration date (or earlier).
    - (2)(g) - log for each CPMP shall be made and filed
      - pt name/address
      - serial number
      - date & expiration date
      - label
      - Pharmacist's initials

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Viernes
Sábado
Domingo
Nombre del paciente

Common Inspection Violations

- Controlled Substance Records
    - DEA form 222 not complete
    - annual inventory not available for inspection
    - invoices not signed (or electronically signed) and dated by a Licensee (pharmacist)

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Common Inspection Violations

- Equipment, Supplies, references, and housing
  - R 338.536 – Housing
    - Clean and sanitary surroundings
    - Sufficient counter space and free movement
    - Floor to ceiling partitions

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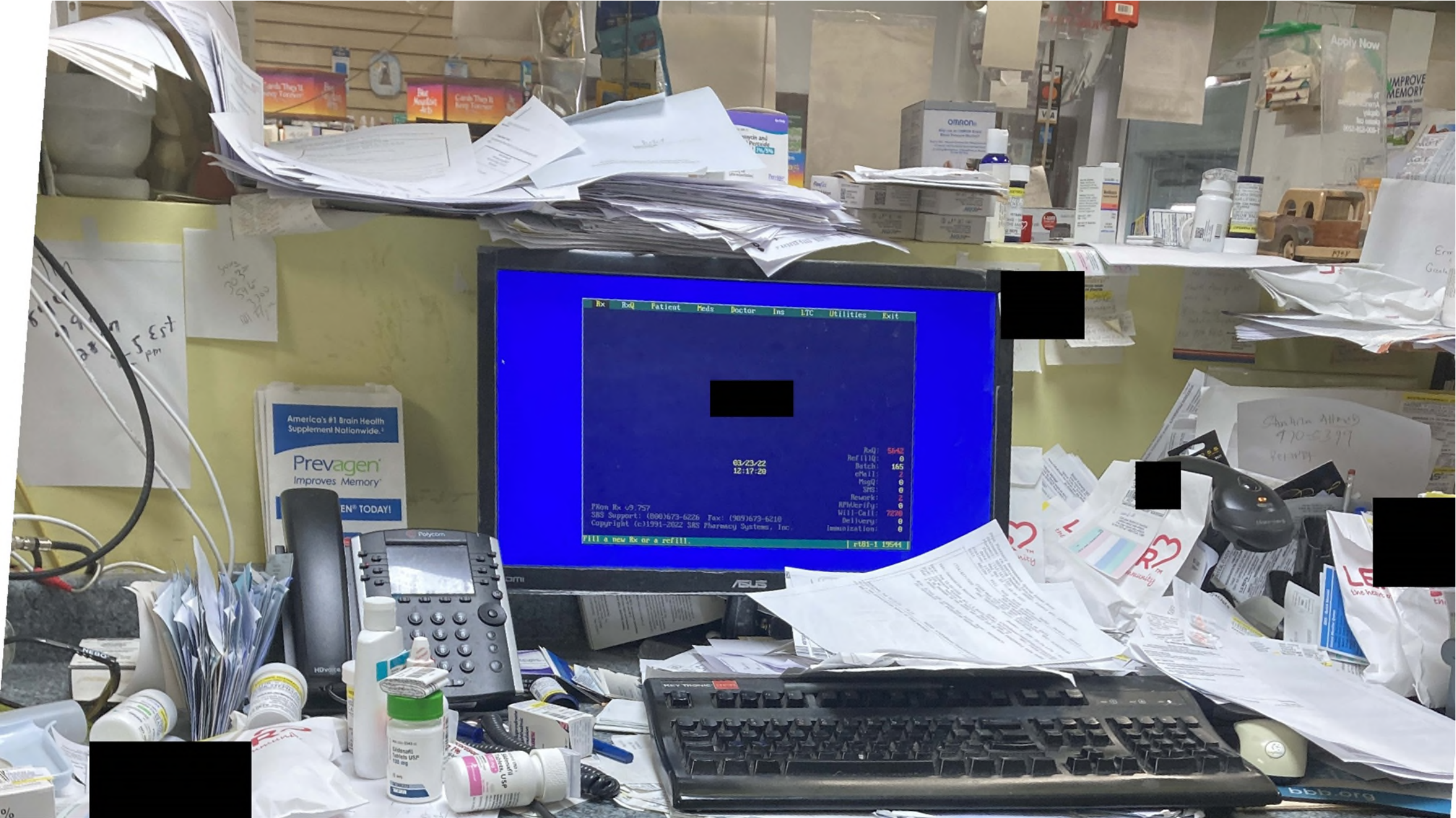
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AROMATHERAPY
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THANK YOU
THANK YOU
THANK YOU
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LEADER


Coffee
FILTERS
BASKET
200
Rugby
Regular Strength
Antacid
Liquid
Antacid and Antigas
Original Flavor
Suboxone
Butalbital,
Caffeine
PINKY

Common Inspection Violations

- Security of Pharmacy and Effective Controls
  - R 338.3141(1) Security of pharmacy and effective controls against theft and diversion
    - MCL 333.17741 – A pharmacy open for business shall be under the personal charge of a pharmacist
    - R 338.3141(2) – report of theft or loss within 10 days to the Department (State of Michigan) by submitting DEA 106 form
    - Ability to reconcile controlled substances
      - Theft/Loss
      - audit

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PHARMACY CONTINUING EDUCATION REVIEW
February 15, 2023

RECOMMENDED APPROVAL(S)

Approval from February 15, 2023 to February 28, 2026.
* Each program listed under the sponsor name will be given a separate approval number.

Corewell Health West – Department of Pharmacy Services

- Pharmacy Grand Rounds – Sickle Cell Crisis – Complex Medication Management (pharmacists) for 1 hour
- Pharmacy Grand Rounds – Research Seminar: Manuscript Writing

Ascension Genesys Hospital

- The ART of HIV Regimens: An HIV Guideline Update (pharmacists and pharmacy technicians) for 1 hour
- TikTok! Look What You Made Me Do (pharmacists and pharmacy technicians) for 1 hour
- Sep'sus': A Gen Z's Guide to Surviving Sepsis (pharmacists) for 1 hour

Ascension St. John Hospital, Department of Inpatient Services

- Aspirin Use in Primary CVD Prevention (pharmacists) for 0.5 hours
- Saving Lives: One Antidote at a Time (pharmacists) for 0.5 hours

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

DIRECTOR'S OFFICE

~~CENTRALIZED PRESCRIPTION PROCESSING~~ **PHARMACY - CENTRAL FILL AND SHARED PHARMACY SERVICES**

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(9)** of the administrative procedures act of 1969,1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the ~~department of community health~~ **department of licensing and regulatory affairs** by sections 16145**,** ~~and~~ ~~17701~~**17753, and 17767** of **the public health code,** 1978 PA 368, MCL 333.16145**,** ~~and~~ ~~333.17701~~ **333.17753,** ~~et seq.~~ and **333.17767, and** Executive Reorganization Order ~~Numbers~~ **Nos.** ~~1996-1~~ **1991-9**, 1996-2, ~~and~~ 2003-1, **and 2011-4,** ~~being~~ MCL ~~330.3101~~ **338.3501**, 445.2001, ~~and~~ 445.2011**, and 445.2030**)

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

PART 1. GENERAL PROVISIONS

R 338.3051 Definitions.

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

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

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

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

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

(d) "Deliver**,**" as used in this part**,** means **the actual, constructive, or attempted transfer of** ~~to issue~~a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. ~~A centralized prescription~~ **Deliver does not include a central fill** ~~processing center~~ **pharmacy** that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent**.** ~~has not met the definition of deliver as defined in this subrule.~~

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

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

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

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

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

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

Rule 2. **(1)** ~~To~~**In addition to these rules, ~~central fill~~ pharmacies must follow all applicable board rules. However, to** the extent that ~~any rule in parts 1 and 2 of~~ ~~the centralized prescription processing~~ **these** rules ~~conflicts~~ **conflict** with other board ~~of pharmacy~~ rules, the provisions in ~~parts 1 and 2 of the centralized prescription processing~~ **these** rules ~~shall~~**must** prevail.

(2) Shared pharmacy services for processing functions of centralized pharmacy processing that do not involve the dispensing process, such as completing claims adjudication or remote data entry, may be performed under the general supervision of a pharmacist. For this subrule, dispensing process means the physical preparing, compounding, packaging, or labeling of a drug product intended for delivery to the patient.

R 338.3053 Centralized prescription processing; **dispensing** requirements.

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

(a) ~~Be licensed by the Michigan board of pharmacy~~**Hold a pharmacy license in this state**.

(b) Share sufficient patient and drug information to minimize the possibility of an adverse drug event.

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

(2) The originating pharmacy shall maintain the original prescription for a period of 5 years after the date the prescription was filled.

(3) Two years after the prescription was filled, the originating pharmacy may make an electronic duplicate of the original paper prescription, which becomes the original prescription. The originating pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or board upon request.

~~(2)~~**(4)** A pharmacy engaging in centralized prescription processing ~~shall be~~**is** responsible for each function of the prescription's processing performed by that pharmacy.

~~(3)~~**(5)** A delivering pharmacist ~~shall be~~**is** responsible for complying with ~~R 338.490(4)~~ **R 338.589(4)** regarding patient counseling.

~~(4)~~**(6)** The prescription label for a prescription that was filled by a ~~centralized prescription processing center~~ **central fill pharmacy** ~~shall~~**must** identify each pharmacy that was involved in ~~preparing~~**dispensing** and delivering ~~a~~**the** prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** may be identified on a prescription label by use of a unique identifier that is recognized by the delivering pharmacist. **A central fill pharmacy shall create and maintain a unique identifier and communicate the unique identifier to all pharmacies that use its services.** As used in this subrule, "unique identifier" means a unique combination of letters, numbers, or symbols that allows the delivering pharmacy to identify the specific ~~centralized prescription processing center~~ **central fill pharmacy** involved in the processing of the prescription. ~~A centralized prescription processing center shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.~~

~~(5)~~**(7)** A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, ~~provided that~~**if** the transfer records are maintained. A ~~centralized prescription processing center~~ **central fill pharmacy** and an originating pharmacy shall establish procedures for the disposition of prescription medication that was not delivered to patients. This medication may be returned to stock and may be ~~re-delivered~~ **re-dispensed** without constituting a violation of R ~~338.472(1)~~ **338.503(1)**.

~~(6)~~**(8)** A pharmacy that performs or contracts for centralized prescription **processing** ~~services~~ shall comply with the procedures described in its policies and procedures manual, ~~as provided in~~**pursuant to** section 17753(2) of the code**, MCL 333.17753**.

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

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

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

(b) The method of transmittal.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART 2. CONTROLLED SUBSTANCES PRESCRIPTIONS

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

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

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

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

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

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

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

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

(b) Ensure that ~~all~~ **the** information that is required ~~to be~~ on a prescription ~~pursuant to~~**under** ~~the provisions of~~ 21 **CFR**~~C.F.R. §~~ 1306.05 and R 338.3161 is transmitted to the ~~centralized prescription processing center~~**central fill pharmacy,** either on the face of the original prescription or in the electronic transmission of **the** prescription~~ information~~.

(c) ~~Indicate~~ **Include all of the following** in the prescription~~ information that is transmitted,~~**:**

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

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

(d) Maintain the original prescription for a period of 5 years from the date the prescription was filled.

(4) Two years after the prescription was filled, the originating pharmacy may make an electronic duplicate of the original printed prescription, which becomes the original prescription. A pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or board upon request.

~~(4)~~**(5)** In addition to complying with the requirements in R ~~338.3053~~**338.3054**(2)(a), (b), (c), (d), (e), (f) and (g), a ~~centralized prescription processing center~~**central fill pharmacy** that receives the transmitted prescription shall comply with ~~both~~**all** of the following:

(a) Maintain records for 5 years after **the date of transmittal**.

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

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

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

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

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PROGRAM FOR UTILIZATION OF UNUSED PRESCRIPTION DRUGS

Filed with the secretary of state on

These rules ~~become effective~~**take effect** immediately ~~after~~**upon** filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145(3), 17701, and 17775 of 1978 PA 368, MCL 333.16145(3), 333.17701, and 333.17775 and Executive Reorganization Order ~~No.~~**Nos. 1991-9, 1996-2, 2003-1, and** 2011-4, **MCL 338.3501, 445.2001, 445.2011, and** ~~MCL~~ 445.2030)

R 338.3601, R 338.3603, R 338.3605, R 338.3607, R 338.3609, R 338.3611, R 338.3615, R 338.3617, R 338.3621, R 338.3625, R 338.3627, R 338.3629, R 338.3631, R 338.3633, R 338.3635, R 338.3637, R 338.3639, R 338.3641, and R 338.3643 of the Michigan Administrative Code are amended, R 338.3621a, R 338.3621b, R 338.3621c, and R 338.3621d are added, and R 338.3613, R 338.3619, and R 338.3623 are rescinded, as follows:

R 338.3601. Definitions.

Rule 1. **(1)** As used in ~~this part~~**these rules**:

~~(a) "Charitable clinic" means a charitable nonprofit corporation or facility that meets all of the following requirements:~~

~~(i) Is organized as a not-for-profit corporation pursuant to the nonprofit corporation act, 1982 PA 162, MCL 450.2101 to 450.3192.~~

~~(ii) Holds a valid exemption from federal income taxation issued pursuant to section 501(a) of the internal revenue code, 26 USC 501.~~

~~(iii) Is listed as an exempt organization under section 501(c) of the internal revenue code, 26 USC 501.~~

~~(iv) Is organized under or operated as a part of a health facility or agency licensed under article 17 of the code, MCL 333.20101 to 333.20211.~~

~~(v) Provides on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at the facility advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health.~~

~~(vi) Has a licensed pharmacy.~~

(~~b~~**a**) "Chemotherapeutic agent" means a chemical agent used for treating various forms of cancer generally by killing the cancer cells.

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

(~~d~~**c**) "Eligible facility" means a medical institution as that term is defined in R 338.486.

(**ed**) “Department” means the department of licensing and regulatory affairs~~, bureau of health care services~~.

~~(f) "Eligible participant" means an individual who meets all of the following requirements:~~

~~(i) Is a resident of this state.~~

~~(ii) Is eligible to receive medicaid or medicare or has no health insurance and otherwise lacks reasonable means to purchase prescription drugs, as prescribed in these rules.~~

(~~g~~**e**) “Hazardous waste” means hazardous waste as **that term is** defined in R 299.9203.

~~(h) "Health professional" means any of the following individuals licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care, or treatment within the scope of his or her professional license:~~

~~(i) A physician licensed to practice medicine or osteopathic medicine and surgery under part 170 or 175 of the code, MCL 333.17001 to 333.17088 or 333.17501 to 333.17556.~~

~~(ii) A physician's assistant licensed under part 170, 175, or 180 of the code; MCL 333.17001 to 333.17088, 333.17501 to 333.17556, or 333.18001 to 333.18058.~~

~~(iii) A dentist licensed under part 166 of the code, MCL 333.16601 to 333.16648.~~

~~(iv) An optometrist licensed under part 174 of the code, MCL 333.17404 to 333.17437.~~

~~(v) A pharmacist licensed under part 177 of the code, MCL 333.17701 to 333.17780.~~

~~(vi) A podiatrist licensed under part 180 of the code, MCL 333.18001 to 333.18058.~~

~~(i) "Program" means the statewide unused prescription drug repository and distribution program known as the program for utilization of unused prescription drugs that is established in section 17775 of the code, MCL 333.17775.~~

(~~j~~**f**) “Unit dose package” means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label.

(~~k~~**g**) “Unit of issue package” means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

(h) “USP” means the United States pharmacopeia.

(i) “USP-NF” means the United States pharmacopeia and the national formulary.

(~~l~~**j**) “Waste disposal facility” means a waste diversion center or disposal facility that is in compliance with the natural resources and environmental protection act, 1994 PA 451, MCL 324.101 to 324.90106, for processing or disposal.

(k) “Original sealed and tamper-evident packaging” shall have the same meaning as “Unopened tamper-evident packaging” as defined in USP, General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning as used in these rules.

R 338.3603. Eligibility criteria; pharmacy; charitable clinics; requirements; withdrawal.

Rule 3. (1) To be eligible for participation in the program **and accept donated prescription drugs**, a pharmacy or charitable clinic shall comply with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold an active, nonrestricted, ~~state of Michigan~~ license **in this state** ~~in good standing~~.

(2) Participation in the program is voluntary.

(3) A pharmacy or charitable clinic may elect to participate in the program **and accept donated prescription drugs** by providing, on a form provided by the department, ~~written notification to the department of~~ all ~~of~~ the following:

(a) The name, ~~street~~ address, ~~and~~ telephone number**, and license number** of the pharmacy **licensed under article 15** or charitable clinic **licensed under article 17**~~, and any state of Michigan license or registration number issued to the pharmacy or charitable clinic~~.

(b) For a charitable clinic, evidence that the charitable clinic meets the requirements ~~defined~~ in ~~R 338.3601(a)~~**section 17775 of the code, MCL 333.17775** .

(c) The name and license number of the responsible pharmacist employed by or under contract with the pharmacy or charitable clinic.

(d) A statement signed and dated by the responsible pharmacist indicating that the pharmacy or charitable clinic meets the eligibility requirements under this rule and shall comply with the requirements of the program.

(4) A **participating** pharmacy or charitable clinic may withdraw from participation in the program ~~at any time~~ by providing written notice to the department on a form provided by the department. All of the following information ~~shall~~**must** be included on the notice of withdrawal form:

(a) Name, address, telephone number, and ~~state of Michigan~~ license ~~or registration~~ number of **the participating** pharmacy or **the** charitable clinic.

(b) Name and dated signature of the responsible pharmacist, attesting that the **participating** pharmacy or charitable clinic ~~will~~**shall** no longer participate in the program.

(c) Date of withdrawal.

R 338.3605 Eligible prescription drugs.

Rule 5. (1) All non-controlled prescription drugs, except those specified in R 338.3607, that have been approved for medical use in the United States, are listed in the ~~United States pharmacopeia and the national formulary (usp-nf)~~**USP-NF**, and meet the criteria for donation established by these rules may be accepted for donation under the program.

(2) A new prescription may be transferred to another participating pharmacy or charitable clinic for dispensing.

R 338.3607. Ineligible drugs; controlled substances prohibited.

Rule 7. (1) The following **drugs** ~~shall~~**must** not be accepted for dispensing under the program:

(a) Controlled substances, as **that term is** defined in article 7 of the code or by federal law.

(b) Expired prescription drugs.

(c) Drugs that may be dispensed only to a patient registered with the drug's manufacturer under **the Federal Food and Drug Administration's** ~~federal food and drug administration~~ requirements.

(d) Drugs that have been ~~held~~ outside of a health professional's control where sanitation and security cannot be assured.

(e) Compounded drugs.

(f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or the ~~usp-nf~~**USP-NF** ~~shall not be donated or accepted as part of the program~~. Excluded from this restriction are drugs donated directly from a drug manufacturer **or an eligible facility has ensured the integrity of the drug by enclosing in the donation packaging a USP-**

recognized method by which the participating pharmacy or charitable clinic can easily detect improper temperature variations.

(2) Controlled substances submitted for donation ~~shall~~**must** be documented and returned immediately to the eligible facility that donated the drugs. Both of the following apply:

(a) If controlled substances enter the participating pharmacy or charitable clinic and it is not possible or practicable to return the controlled substances to the donating facility, abandoned controlled substances ~~shall~~**must** be documented and destroyed ~~pursuant to~~**under** the protocols currently used by the **participating** pharmacy.

(b) A destruction record ~~shall~~**must** be created and maintained for a period of 5 years after destruction ~~for~~ **of** ~~any~~**a** controlled **substance**~~substances destroyed~~. **Two years after the date of the destruction, the participating pharmacy or charitable clinic may make an electronic duplicate of the original record, which becomes the original record of destruction. A participating pharmacy shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

R 338.3609 Donated prescription drugs; participating pharmacy or charitable clinic requirements.

Rule 9. (1) A participating pharmacy or charitable clinic may accept a prescription drug only if all of the following requirements are met:

(a) The drug is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose, unit of issue package, or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging or unit of issue packaging is unopened.

(b) The drug has been stored according to manufacturer or ~~usp-nf~~**USP-NF** storage requirements.

(c) The packaging contains the ~~lot number and~~ expiration date of the drug. If the lot number is not retrievable, all specified medications ~~shall~~**must** be destroyed ~~in the event of~~**if there is** a recall.

(d) The drug **is not expired.** ~~has an expiration date that is more than 6 months after the date that the drug was donated.~~

(e) The drug does not have ~~any~~ physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated.

(f) The packaging does not have ~~any~~ physical signs of tampering, deterioration, compromised integrity, or adulteration.

(2) A participating pharmacy or charitable clinic may accept donated prescription drugs from more than 1 eligible facility, ~~provided that~~**if** the **prescription drugs are donated** ~~donating is done pursuant~~**under** ~~to~~ the terms of the program.

R 338.3611 Donated prescription drugs; eligible facility**, manufacturer** requirements.

Rule 11. (1) An eligible facility or manufacturer may donate unused or donated prescription drugs, other than controlled substances, to a participating pharmacy or charitable clinic, if the drug meets the requirements of these rules.

(2) A manufacturer or its representative may donate prescription drugs in complimentary starter doses, other than controlled substances, to a charitable clinic under the program, if the drug meets the requirements of these rules.

R 338.3613 ~~Resident of eligible facility; donations permitted.~~ **Rescinded.**

~~Rule 13. (1) A resident of an eligible facility or the representative or guardian of a resident of an eligible facility may donate unused prescription drugs to be dispensed under the terms of the program.~~

~~(2) A resident of an eligible facility or the resident's representative or guardian shall complete a resident donation form prior to the eligible facility taking possession of the drugs to be donated. A copy of the resident donation form shall be sent to the participating pharmacy or charitable clinic with the donated drugs.~~

~~(3) The prescription drugs donated under the method described in this rule shall have originated from the eligible facility, and prescription drugs obtained prior to the resident being admitted to the facility shall not be accepted.~~

~~(4) The prescription drugs donated under the method described in this rule are subject to all the requirements of these rules.~~

R 338.3615 Transfer and shipment of donated drugs; requirements.

Rule 15. (1) ~~Prior to the initial~~ **The eligible facility or manufacturer shall complete and transmit the eligible facility or manufacturer donation form or a substantively similar electronic or physical form in each shipment of donated prescription drugs to the participating pharmacy or charitable clinic.** ~~transfer of~~ donated drugs ~~from an eligible facility or manufacturer to a participating pharmacy or charitable clinic, the eligible facility or manufacturer shall complete the eligible facility donation form. The eligible facility or manufacturer shall transmit the completed eligible facility donation form to the participating pharmacy or charitable clinic and retain a copy for its records.~~

~~(2) A completed transfer form shall be included in each shipment of donated drugs from an eligible facility or manufacturer to a participating pharmacy or charitable clinic.~~

(~~3~~**2**) Donated drugs under the program ~~shall~~**must** be shipped from the eligible facility or manufacturer to the participating pharmacy or charitable clinic via common or contract carrier.

R 338.3617 Inspection and storage of donated prescription drugs; destruction; recall.

Rule 17. (1) ~~A~~**Prior to dispensing a donated drug a** licensed pharmacist employed by or under contract with the participating pharmacy or charitable clinic shall inspect donated prescription drugs to determine, in the professional judgment of the pharmacist, that the drugs are not adulterated, are safe and suitable for dispensing, and are eligible drugs. ~~The pharmacist who inspects the drugs shall sign the transfer form included with the shipment of donated drugs attesting to the above.~~

(2) The participating pharmacy or charitable clinic shall store donated drugs ~~pursuant to~~**under** the manufacturer's guidelines or ~~usp-nf~~**USP-NF** guidelines. Donated drugs ~~shall~~**must be stored and maintained in a manner that distinguishes them physically or electronically from other non-donated inventory.** ~~not be stored with non-donated inventory at any time.~~

(3) ~~When~~**If** donated drugs are not inspected immediately upon receipt, a participating pharmacy or charitable clinic shall ~~quarantine~~**store** the donated **prescription** drugs separately from all dispensing stock until the donated **prescription** drugs have been inspected and approved for dispensing under the program.

(4) A participating pharmacy or charitable clinic shall destroy donated prescription drugs that are not suitable for dispensing ~~pursuant to~~**under the** protocols currently established by the pharmacy or charitable clinic for the destruction of prescription drugs.

(5) A participating pharmacy or charitable clinic shall create and maintain a destruction and disposal record for donated **prescription** drugs that are destroyed and disposed of as a result of being expired, adulterated, recalled, or otherwise not eligible for dispensing. A participating pharmacy or charitable clinic shall maintain a destruction record for 5 years after destruction of the donated drugs. **Two years after the destruction of the donated drugs, the participating pharmacy or charitable clinic may make an electronic duplicate of the original record, which becomes the original record. A participating pharmacy or charitable clinic shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

(6) If a participating pharmacy or charitable clinic receives a recall notification, the participating pharmacy or charitable clinic shall perform a uniform destruction of all ~~of~~ the recalled prescription drugs in the participating pharmacy or charitable clinic and complete the destruction record for all donated **prescription** drugs **that are** destroyed. The destruction ~~shall~~**must** be done ~~pursuant to~~**under the** protocols currently established by the pharmacy or charitable clinic for the destruction and disposal of prescription drugs.

(7) If a recalled drug has been dispensed, the participating pharmacy or charitable clinic shall immediately notify the eligible participant of the recalled drug ~~pursuant to~~**under** established drug recall procedures.

(8) Notwithstanding any rule to the contrary, a participating pharmacy may repackage a donated prescription drug or medical supply as necessary for storage, dispensing, administration, or transfers in accordance with the following:

(a) Repackaged medicine shall be labeled with the drug name, strength, and expiration date and shall be kept in a separate designated area until inspected and initialed by a health care professional.

(b) If multiple packaged donated medicines with varied expiration dates are repackaged together, the shortest expiration date shall be used.

R 338.3619 ~~Record keeping; inventory; requirements.~~ **Rescinded.**

~~Rule 19. (1) A participating pharmacy or charitable clinic shall keep records in conform with these rules and all applicable federal and state laws, rules, and regulations.~~

~~(2) A participating pharmacy or charitable clinic shall maintain documented policies and procedures that will address all the requirements of these rules.~~

~~(3) A participating pharmacy or charitable clinic shall document all of the following for each drug accepted for the program:~~

~~(a) Brand name or generic name of the drug.~~

~~(b) Name of the manufacturer or national drug code number (ndc#).~~

~~(c) Quantity and strength of the drug.~~

~~(d) Lot number of medication if available.~~

~~(e) Expiration date of medication.~~

~~(f) Date the drug was donated and the date the drug was subsequently dispensed.~~

~~(g) Name of the eligible facility that donated the drug and the eligible participant subsequently dispensed the drug.~~

~~(h) The prescription from a health care professional.~~

~~(4) All records required for participation in the program shall be maintained separate from other records for 5 years and shall be readily retrievable for inspection at the request of the department or its agent.~~

R 338.3621 Forms; ~~eligible facility donation form,~~ **manufacturer donation form,** ~~resident donation form, eligible participant form, transfer form, destruction form;~~ **general** requirements.

Rule 21. (~~6~~**1**) All forms required for participation in the program must be maintained separate from other records for 5 years**.** ~~and shall be readily retrievable for inspection at the request of the department or its agent.~~ **Two years after the record is made, the holder of the record may make an electronic duplicate of the original record, which becomes the original record. The holder of the record shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

(~~7~~**2**) The department shall make available all forms required by the program. The forms ~~shall~~must be available at no cost from the Department of Licensing and Regulatory Affairs, ~~Bureau of Health Care Services~~, 611 ~~W.~~West Ottawa ~~St.~~Street, Lansing, ~~MI~~Michigan 48909 or on the department's website at ~~www.michigan.gov/healthlicense~~ https://www.michigan.gov/lara/bureau-list/bpl/resources/special-programs/cancer-drug-repository-program-and-utilization-of-unused-prescription-drugs-program?sc_site=lara. **A participant of the program may also use a substantively similar electronic or physical form for all forms required by the program.**

(3) A participating pharmacy or charitable clinic shall maintain documented policies and procedures that address all the requirements of these rules.

(4) A participating pharmacy or charitable clinic shall keep records as required under these rules and all applicable federal and state laws, rules, and regulations.

~~(1) An eligible facility donation form shall include all of the following information:~~

~~(a) An eligible facility's or manufacturer's name, address, and telephone number; the name, dated signature, and license number of pharmacist or health care provider authorized to donate the drugs; and, the license number of the facility or manufacturer.~~

~~(b) A statement of the facility's intent to participate in the program and donate eligible prescription drugs to the participating pharmacy or charitable clinic identified on the form.~~

~~(c) The receiving participating pharmacy's or charitable clinic's name, address, and telephone number.~~

~~(d) The name, state of Michigan license number, and dated signature of the responsible pharmacist authorized to receive the donation.~~

~~(e) The date the donation was received.~~

~~(2) A resident donation form shall include all of the following information:~~

~~(a) The eligible facility's name, address, state of Michigan license or registration number, and telephone number; and the name, dated signature, and license number of pharmacist or health care provider authorized to donate the drugs.~~

~~(b) The resident's name and dated signature, or the name and dated signature of the resident's representative or guardian.~~

~~(c) Attestation to the following statement, "As the legal owner of the listed prescription drug(s), I agree to voluntarily donate the listed eligible unused drugs to the program for utilization of unused prescription drugs."~~

~~(d) The drug brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(e) The date of the donation.~~

~~(f) The name, address, telephone number and state of Michigan license or registration number of the pharmacy or charitable clinic receiving donated unused prescription drug.~~

~~(g) The date the donated drugs are received by the pharmacy or charitable clinic.~~

~~(h) The name, state of Michigan license or registration number, and dated signature of the authorized pharmacist or health care provider receiving the donated prescription drug.~~

~~(3) The eligible participant form shall include all of the following information:~~

~~(a) The participating pharmacy's or charitable clinic's name, address, telephone number, state of Michigan license or registration number, and the name, state of Michigan license or registration number, and dated signature of dispensing pharmacist.~~

~~(b) The drug's brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, the date the drug was dispensed, and the drug's expiration date.~~

~~(c) The eligible participant's name, date of birth, address, and dated signature.~~

~~(d) Attestation of all of the following:~~

~~(i) The eligible participant is a resident of this state.~~

~~(ii) The eligible participant is eligible to receive medicare or medicaid or is uninsured and does not have prescription drug coverage.~~

~~(e) The eligible participant acknowledges that the drugs have been donated.~~

~~(f) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the poison prevention packaging act, being 15 U.S.C. §1471–1477.~~

~~(4) The transfer form shall include all of the following information:~~

~~(a) The eligible facility or manufacturer's name, state of Michigan license or registration number, address, telephone number, and the name, dated signature, and state of Michigan license number of the responsible pharmacist.~~

~~(b) The date of donation.~~

~~(c) The drug's brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(d) The pharmacist of the eligible facility or manufacturer shall attest to the following statement, "I certify that the prescription drugs listed on this form for donation are eligible for donation and meet the requirements for prescription drugs under the program, including any storage requirements."~~

~~(e) The receiving participating pharmacy's or charitable clinic's name, address, and telephone number, and name and state of Michigan license number of responsible pharmacist authorized to receive the donation.~~

~~(f) The responsible pharmacist shall sign and date the transfer form attesting to the following statement, "Upon receipt and inspection of the above listed donated prescription drugs, it is in my professional judgment that these drugs are not adulterated, are safe and suitable for dispensing, and are eligible drugs."~~

~~(5) The destruction form shall include all of the following:~~

~~(a) The participating pharmacy's or charitable clinic's name, state of Michigan license number, address, telephone number, the name, dated signature, and license number of the responsible pharmacist.~~

~~(b) The drug's brand name or generic name, the name of the manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(c) The reason for destruction of the drug.~~

~~(d) The name, title, and dated signature of the witness.~~

~~(e) The date of destruction.~~

~~(f) If off-site disposal is used, the name of the firm destroying or disposing the drug, the name and dated signature of the person at the firm destroying or disposing the drug, and the date of disposal.~~

R 338.3621a Eligible facility donation form, manufacturer donation form; requirements.

Rule 21a. (1) An eligible facility or manufacturer donation form must include all of the following information:

(a) The following information for the eligible facility or manufacturer that will donate prescription drugs:

(i) The name, address, telephone number, and license number.

(ii) The name, dated signature, and license number of the pharmacist or healthcare provider authorized to make the donation, if applicable.

(b) A statement of the eligible facility or manufacturer's intent to participate in the program and donate to the participating pharmacy or charitable clinic identified on the form.

(c) The name, address, and telephone number of the participating pharmacy or charitable clinic that will receive the donation.

(d) The name, license number, and dated signature of the pharmacist authorized to receive the donation.

(e) The date the donation was received by the participating pharmacy or charitable clinic.

R 338.3621b Eligible participant form; requirements.

Rule 21b. (1) The eligible participant form must include all of the following information prior to receiving the first donated prescription drug:

(a) An attestation from the eligible participant that includes all the following:

(i) The eligible participant is a resident of this state.

(ii) The eligible participant is eligible to receive medicare or medicaid or is uninsured and does not have prescription drug coverage.

(b) The eligible participant acknowledges that the drug is donated.

(c) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the Poison Prevention Packaging Act, 15 USC 1471 to 1477.

R 338.3621c Transfer form; requirements.

Rule 21c. (1) A participating pharmacy or charitable clinic shall document all of the following for all donations made to the program on a transfer form:

(a) The following information for each prescription drug:

(i) Brand name or generic name of the drug.

(ii) Name of the manufacturer or national drug code number (ndc#).

(iii) Quantity and strength of the drug.

(iv) Date the drug was donated.

(v) Name of the eligible facility that donated the drug.

(b) The name, address, telephone number, and license number of the participating pharmacy or charitable clinic receiving the donated prescription drug.

(c) The name and license number of the responsible pharmacist authorized to receive the donated prescription drug.

(d) The pharmacist or facility manager responsible for the eligible facility or manufacturer shall attest to the following statement, "I certify that the prescription drugs for donation are eligible for donation and meet the requirements for prescription drugs under the program, including storage requirements."

R 338.3621d Destruction form; requirements.

R 21d. (1) The destruction form must include all of the following:

(a) The name, address, telephone number, and license number of the participating pharmacy or charitable clinic.

(b) The name, license number, and dated signature of the responsible pharmacist.

(c) The following information for each donated prescription drug that is destroyed:

(i) The brand name or generic name of the drug.

(ii) The name of manufacturer or national drug code number (ndc#).

(iii) The quantity and strength of the drug.

R 338.3623 ~~Eligible participants; requirements.~~ **Rescinded.**

~~Rule 23. The eligible participant shall complete the eligible participant form attesting to the following statements:~~

~~(a) The eligible participant is a resident of the state of Michigan.~~

~~(b) The eligible participant is eligible to receive medicare or medicaid or does not have insurance or prescription drug coverage. Verification or written documentation shall not be required.~~

~~(c) The eligible participant acknowledges that the drugs have been donated.~~

~~(d) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the poison prevention packaging act, 15 U.S.C. §1471–1477.~~

R 338.3625 Dispensing donated prescription drugs; requirements.

Rule 25. (1) A participating pharmacy or charitable clinic shall dispense **a** donated prescription ~~drugs~~**drug** in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(~~3~~**2**) The ~~department and a local~~ participating pharmacy or charitable clinic shall remove ~~any~~ patient identifying information from the package ~~prior to~~**before** dispensing the drug~~s~~.

(4**3**) **A participating pharmacy or charitable clinic shall not resell a** ~~Prescription drugs~~ donated **prescription drug** ~~under this program shall not be resold~~; however, a participating pharmacy or charitable clinic may collect a handling fee ~~pursuant to~~**under** ~~the terms of~~ R 338.3627.

R 338.3627 Handling fee.

Rule 27. (1) A participating pharmacy or charitable clinic may charge the eligible participant receiving a donated **prescription** drug a handling fee, not to exceed **the reasonable costs of participating in the program, including, but not limited to, the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies, and equipment.** ~~a maximum of 300% of the medicaid standard pharmacy dispensing fee as established by the Michigan department of community health, to cover stocking and dispensing costs., provided that the~~ **A participating pharmacy or charitable clinic shall use reasonable efforts to ensure the** handling fee does not exceed the total cost of obtaining the **same** drug outside the program.

(2) A copy of the medicaid drug dispensing fees can be obtained from the Michigan department of **health and human services** ~~community health, 201 Townsend Street, Lansing, Michigan 48913 or on the department's website at http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-151019--,00.html~~.

(3) A **handling fee charged for a donated** prescription drug dispensed through the program ~~shall~~**is** not ~~be~~ eligible for reimbursement under the medical assistance program.

(4) The eligible participant shall not be charged a handling fee if the eligible participant is receiving a professional sample which is distributed to patients at the same charitable clinic whom are ineligible for the program without a handling fee.

R 338.3629 Donation to other participating pharmacy or charitable clinic.

Rule 29. ~~The originating~~ **A** participating pharmacy or charitable clinic may donate **prescription** drugs **that they have received** ~~donated~~ under ~~this~~ **the** program to other participating pharmacies or charitable clinics for use ~~pursuant to~~**under** the program. The participating pharmacy or charitable clinic donating the **prescription** drugs shall complete a transfer form **required under R 338.3621c**.

R 338.3631 Registry; creation.

Rule 31. The department shall establish and maintain a participating pharmacy and charitable clinic registry for the program on the department's website. The registry ~~shall~~**must** include the **name, address, and telephone number of the** participating pharmacy~~'s~~ or charitable clinic **and** ~~'s name, address, and telephone number, and the contact name of~~ the **name of the** responsible pharmacist.

R 338.3633 Collection of prescription drugs and other medication for destruction and disposal; requirements; limitations.

Rule 33. (1) ~~Pursuant to~~**Under** section 17776 of the code, MCL 333.17776, a participating pharmacy or charitable clinic shall accept from ~~any~~**a** person a prescription drug or ~~any other~~**another** medication that is ineligible for distribution under the program for destruction and disposal.

(2) Unless ~~permitted~~**allowed** by federal law, controlled substances ~~shall~~**must** not be collected by a participating pharmacy or charitable clinic for destruction and disposal.

(3) If a participating pharmacy or charitable clinic accepts a chemotherapeutic agent for destruction, the chemotherapeutic agent ~~shall~~**must** not be mixed with other prescription drugs

collected for disposal under the program. The chemotherapeutic agent ~~shall~~**must** be mixed with the participating pharmacy's or charitable clinic's hazardous waste.

(4) ~~The~~ **A participating pharmacy or charitable clinic that collects prescription drugs and other medications for destruction and disposal shall collect the prescription drugs and medications** ~~collection shall occur~~ on-site at the participating pharmacy or charitable clinic and **shall follow** ~~according to~~ these rules and all applicable state and federal laws and regulations.

R 338.3635 Collection device; requirements.

Rule 35. A participating pharmacy or charitable clinic shall utilize a collection device to collect prescription drugs and other medications that are ineligible for distribution under the program for destruction and disposal that meets all ~~of~~ the following ~~criteria~~**requirements**:

(a) Is designed to allow **prescription drugs and other medications to be added to the device but allow only authorized personnel to remove the** contents **from the collection device** ~~to be added to the device but not removed, except by authorized personnel~~ for ~~the purpose of~~ destruction and disposal.

(b) Is labeled ~~pursuant to~~**consistent with** all applicable state and federal laws and regulations~~.~~ **and contains the following statement prominently on the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless allowed under federal law." and "Chemotherapeutic agents must not be placed in this collection device."**

(c) Is lined with a removable liner that is waterproof, tamper-evident, tear resistant, and capable of being sealed.

(d) The contents of the ~~liner~~**collection device must**~~shall~~ not be viewable from the outside **of the collection device** and the size or capacity of the ~~liner shall~~ **collection device must** be clearly marked on the outside of the ~~liner~~**collection device**.

~~(d) Is secured in a manner that will only allow authorized personnel to remove the contents of the container for the purpose of destruction and disposal.~~

(e) ~~Uses a design that is~~ **Is** tamper resistant and is securely locked.

(f) Is securely fastened to **a** permanent structure within the designated pharmacy area so that it cannot be removed.

(g) Is ~~consistently~~ monitored by security features and pharmacy personnel.

(h) The following statements ~~shall be prominently placed on the collection device and~~ ~~shall~~ **must** be posted as signage near the location of the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless ~~permitted~~**allowed** under federal law." and "Chemotherapeutic agents ~~shall~~**must** not be placed in this collection device."

~~(i) The collection device for the yellow jug old drugs program operated by the Great Lakes clean water organization is deemed to satisfys the requirements of this rule, provided the participating pharmacy or charitable clinic is a compliant participant in the yellow jugs old drugs program.~~

R 338.3637 Access; destruction of collected drugs.

Rule 37. (1) ~~A~~ **An individual shall access a** collection device utilizing a removable liner ~~shall~~ only ~~be accessed~~ for the following purposes:

(a) To remove the contents ~~to process~~ for safe, effective, and immediate transportation.

(b) To immediately transfer the contents to a waste disposal facility.

(c) To immediately transfer the contents to a responsible ~~third party~~**individual** for transportation to a waste disposal facility.

(2) A collection device utilizing a removable liner ~~shall~~**must** only be accessed as follows:

(a) The access ~~shall~~**must** be done by ~~two~~**2** personnel, ~~one~~**1** of whom ~~shall be~~**is** a licensed pharmacist, designated by the participating pharmacy or charitable clinic.

(b) Upon being accessed, the liner ~~shall~~**must** be immediately sealed and the weight of the contents immediately recorded in the destruction and disposal log. A copy of the destruction log ~~shall~~**must** be transferred with the sealed contents.

~~(3) A collection device for the yellow jug old drugs program operated by the Great Lakes clean water organization shall be weighed at the time the collection device leaves the pharmacy and the weight shall be recorded in the destruction and disposal log. The participating pharmacy or charitable clinic shall comply with all requirements of the yellow jug old drugs program.~~

(4**3**) Within 1 year of collection, the contents of the collection device ~~shall~~**must** be transferred to a waste disposal facility for destruction.

(~~5~~**4**) The contents of the collection device ~~shall~~**must**be destroyed ~~pursuant to~~**under** all applicable state and federal laws and regulations.

R 338.3639 Record keeping; policy and procedures; destruction and disposal log.

Rule 39. (1) ~~In addition to the policy and procedure requirements in R 338.3617 and R 338.3619, a~~ **A** participating pharmacy or charitable clinic shall maintain a destruction and disposal log that includes all of the following information:

(a) **The name**~~Name~~, telephone number, address, and ~~state of Michigan~~ license ~~or registration~~ number of the participating pharmacy or charitable clinic.

(b) **The date**~~Date~~, time, **and** weight of the contents of the collection device each time the contents of the collection device are removed for destruction.

(c) The name, telephone number**,** and address of ~~any~~**a person** ~~third party~~ responsible for transporting the contents to the waste disposal facility.

(d) The name, telephone number**,** and address of the waste disposal facility where the contents of the collection device were transferred.

(2) Copies of all contracts with transporters and waste disposal facilities ~~shall~~**must** be stored with the destruction log, as applicable.

R 338.3641 Transportation.

Rule 41. The contents of the collection device ~~shall~~**must** be transferred to a waste disposal facility ~~pursuant to~~**under** all applicable state and federal laws and regulations.

R 338.3643 Department of **health and** human services ~~and department of community health~~; inclusion in rule-making process.

Rule 43. The department shall notify the director of the department of **heath and** human services ~~and the director of the department of community health~~ of an approved request for rule-making under MCL 24.239 for rule promulgation affecting eligible facilities or mental health or substance abuse clients. The department of **health and** human services ~~and the department of community health~~ shall provide ~~any~~ input regarding the rule promulgation to the department within 30 days ~~of~~**after** receipt of notification of the approved request for rule-making.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY – CONTROLLED SUBSTANCES

Filed with the secretary of state on

These rules ~~take effect~~**become effective** immediately ~~upon~~**after** filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the **director of the department of licensing and regulatory affairs and the** board of pharmacy by sections 7106, 7109, 7203, 7216, 7301, 7303, 7303a, 7321, 7333, 7333a, and 17754 of the public health code, 1978 PA 368, MCL 333.7106, 333.7109, 333.7203, 333.7216, 333.7301, 333.7303, 333.7303a, 333.7321, 333.7333, 333.7333a, and 333.17754, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3101, R 338.3102, R 338.3104, R 338.3108, R 338.3111, R 338.3132, R 338.3135, R 338.3141, R 338.3143, R 338.3145, R 338.3151, R 338.3153, R 338.3153a, R 338.3154, R 338.3161, R 338.3161a, R 338.3162, R 338.3162a, 338.3162b, R 338.3162c, R 338.3162d, R 338.3163, R 338.3164, R 338.3165, R 338.3166, R 338.3167, R 338.3170, R 338.3181, R 338.3183, and R 338.3185, of the Michigan Administrative Code are amended, and R 338.3137 is rescinded as follows:

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

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

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

(~~b~~**c**) "Board" means the board of pharmacy.

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

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

(f) "CSA" means the Controlled Substance Act of 1970, 21 USC 801.

(g) "DEA" means the Federal Drug Enforcement Administration.

(~~d~~**h**) "Department" means the department of licensing and regulatory affairs ~~(LARA)~~.

(~~e~~**i**) "Electronic signature" means an electronic sound, symbol, or process attached to or ~~logically~~ associated with a record and executed or adopted by an individual with the

intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures ~~such~~ that ~~it~~ is only available for use by the intended individual and ensures nonrepudiation so that the signature may not be rejected based on its validity.

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

(k) "FDCA" means the Federal Food, Drug, and Cosmetic Act of 2017, 21 USC 360.

R 338.3102 Definitions; I to P.

Rule 2. As used in these rules:

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

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

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

(~~c~~**d**) "~~Michigan automated prescription system (~~MAPS~~)~~ claim form" means a form, to be determined by the department~~,~~ that is in the format and includes the information as specified by the ~~American Society for Automation in Pharmacy (~~ASAP~~)~~ 4.1 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.

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

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

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

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

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

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

(A) A state-issued driver's license number obtained from a state-issued driver's license.

(B) A state-issued identification number obtained from a state-issued photo identification card.

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

(D) The number zero. Zeroes must be entered as the identification number, if the positive identification presented for the patient or client does not include a license number, identification number, or passport number as listed in subparagraphs (A) to (C) of this paragraph, the patient is under the age of 16, or the animal's owner cannot be identified.

(i) ~~"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.~~

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

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

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

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

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

(b) "Substance" means a controlled substance unless the context indicates otherwise.

R 338.3108 Terms defined in code.

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

PART 2. SCHEDULES

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

Rule 11. (1) The board approves and adopts by reference the complete list of drugs and other substances that are considered controlled substances under the ~~Controlled Substance Act (~~CSA~~)~~ of 1970, 21 USC 801, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15, except for those drugs or other substances specifically excepted by this state's laws enacted after the effective date of these rules or as listed in subrule (3) of this rule.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm, or at 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

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

Substance	1	2	3	4	5
Brorphine	x				
Synthetic Cannabinoid 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),	x				

and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation: (i) Any compound containing a 3-(1-naphthoyl)indole structure, also known as napthoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-007, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398, AM-1220, AM-2201, and WIN-55, 212-2. (ii) Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure, also known as napthylmethylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-175, and JWH-184. (iii) Any compound containing a 3-(1-naphthoyl)pyrrole structure, also known as naphthoylpyrroles with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2- piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the pyrrole ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-370, JWH-030. (iv) Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indene ring to any extent and whether or not substituted on the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-176. (v) Any compound containing a 3-phenylacetylindole structure, also known as phenacetylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-8 (SR-18), JWH-250, JWH-203, JWH-251, and JWH-302. (vi) Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure, also known as cyclohexylphenols, with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, Rendered Thursday, March 17, 2022 Page 10 Michigan Compiled					

Laws Complete Through PA 34 of 2022 ☐ Courtesy of www.legislature.mi.gov whether or not substituted on the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP-47,497 (and homologues(analogs)), cannabicyclohexanol, and CP-55,940. (vii) Any compound containing a 3-(benzoyl)indole structure, also known as benzoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent. Examples of this structural class include but are not limited to: AM-694, pravadoline (WIN-48,098), RCS-4, AM-630, AM-679, AM-1241, and AM-2233. (viii) Any compound containing a 11-hydroxy-/\8-tetrahydrocannabinol structure, also known as dibenzopyrans, with further substitution on the 3-pentyl group by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkyethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group. Examples of this structural class include but are not limited to: HU-210, JWH-051, JWH-133. (ix) Any compound containing a 3-(L-adamantoyl)indole structure, also known as adamantoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the adamantyl ring system to any extent. Examples of this structural class include but are not limited to: AM-1248. (x) Any other synthetic chemical compound that is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring cannabinoids that is not listed in schedules II through V and is not approved by the federal food and drug administration as a drug.					
Synthetic Cathinone 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	x				

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.					
Ephedrine A salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine except for the following: A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is not included in schedule 5 if the drug product meets all of the following criteria: (i) May lawfully be sold over the counter without a prescription under federal law. (ii) Is labeled and marketed in a manner consistent with the pertinent over-the- counter tentative final or final monograph. (iii) Is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse. (iv) Is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement. (v) The drug product is 1 of the following: (A) A solid dosage form, including, but not limited to, a soft gelatin caplet that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose and is packaged in blister packs with not more than 2 tablets or caplets per blister. (B) An anorectal preparation containing not more than 5% ephedrine. (C) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria: (I) Contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids in applicable regulations adopted by the Federal Food and Drug Administration (FDA) and contains no other controlled substance. (II) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids. (III) Is packaged with a prominent label securely affixed to each package that includes all of the following: (1) The amount in milligrams of ephedrine in a serving or dosage unit. (2) The amount of the food product or dietary supplement that constitutes a serving or dosage unit. (3) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable					x

regulations adopted by the FDA. (4) That improper use of the product may be hazardous to an individual's health.					
Isomers Includes the optical, position, and geometric isomers.	x				
Marijuana Including pharmaceutical-grade cannabis, as those terms are defined in parts 71 and 81 of the code, MCL 333.7101 to 333.7125 and MCL 333.8101 to 333.8119, if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the code and as allowed by federal authority but only for the purpose of treating a debilitating medical condition as that term is defined in section 3(b) of the Michigan medical marihuana act, 2008 IL 1, MCL 333.26423, and as allowed under the code.		x			
Salvia divinorum All parts of the plant presently classified botanically as salvia divinorum, whether growing or not; the leaves and seeds of that plant; any extract from any part of that plant; and every compound, salt, derivative, mixture, or preparation of that plant or its leaves, seeds, or extracts.	x				
Salvinorin A	x				
Tianeptine sodium By whatever official, common, usual, chemical, or brand name designated.		x			

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

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

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

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

~~(e) Pentazocine is a schedule 4 controlled substance.~~

~~(f) Brorphine is a schedule 1 controlled substance.~~

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

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

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

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

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

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

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

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

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

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

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

~~(II) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids.~~

~~(III) Is packaged with a prominent label securely affixed to each package that includes all of the following:~~

~~(1) The amount in milligrams of ephedrine in a serving or dosage unit.~~

~~(2) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.~~

~~(3) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable regulations adopted by the FDA.~~

~~(4) That improper use of the product may be hazardous to an individual's health.~~

PART 3. LICENSES

R 338.3132 Controlled substance license.

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

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

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

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

(b) Manufacturing and distributing a controlled substance in schedules 2-5. An individual, partnership, cooperative, association, private corporation, other legal entity, or

governmental entity that is licensed in this state to manufacture a controlled substance listed in schedules 2 to 5 may also conduct chemical analysis and research with a substance that is listed in the schedules under the same controlled substance license.

(c) Dispensing a controlled substance listed in schedules 2 to 5. A prescriber or practitioner who is licensed in this state to prescribe or dispense controlled substances listed in schedules 2 to 5 may also prescribe, dispense, administer, and conduct research with those substances under the same controlled substance license.

(d) Conducting research and instructional activity with a controlled substance listed in schedule 1. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to conduct research with controlled substances listed in schedule 1 may do both of the following:

(i) Manufacture the specific substances as set forth in the research protocol that is filed and approved by the FDA and the DEA ~~pursuant to~~**under** ~~the provisions of~~ 21 CFR 1301.18 and submitted to the department with the application for licensure.

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

(e) Conducting research with a controlled substance listed in schedules 2 to 5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity who is licensed in this state to conduct research with the controlled substances listed in schedules 2 to 5 may also participate in all of the following activities:

(i) Conduct chemical analysis with the specific substances listed in those schedules.

(ii) Manufacture the specific substances if, and to the extent that, the manufacture of the specific controlled substances is set forth in a statement filed with the application for licensure.

(iii) Distribute the specific substances to others who are licensed in this state to conduct research, chemical analysis, or instructional activity with the substances.

(iv) Conduct instructional activities with the specific substances.

(f) Conducting instructional activities with a specific controlled substance listed in schedules 2 to 5.

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

(h) A pharmacy stocking patient medication in an automated device located at an affiliated hospital location ~~pursuant to~~**under** section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in section 20109 of the code, MCL 333.20109. The pharmacy responsible for the device shall obtain an additional controlled substance license for each location. If substances are stored at a health facility without an onsite pharmacy or an automated device stocked by a pharmacy, a designated prescriber shall obtain a controlled substance license **for the address where the drugs will be stored**.

(4) An applicant shall obtain a separate controlled substance license for each practitioner license issued under article 15 of the code, MCL 333.16101 to 333.18838. The controlled

substance license must be renewed ~~when~~**if** the article 15 license is renewed and the controlled substance license is renewed for an equal number of years as the article 15 license.

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**the** application required under subrule (1) of this rule:

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

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

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

(6) An applicant who intends to conduct instructional activity involving controlled substances shall submit all of the following information with ~~his or her~~ **the** application required under subrule (1) of this rule:

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

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

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

(7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with ~~his or her~~**the** application required under subrule (1) of this rule:

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

(b) The protocol and description of the nature of the chemical analysis that is filed and approved by the FDA and the DEA ~~pursuant to~~**under** ~~the provisions of~~ 21 CFR 1301.18.

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

(8) A prescriber or practitioner who is licensed in this state to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations is not required to obtain a separate controlled substance license for each additional physical location of the business or professional practice if the prescriber or practitioner only prescribes controlled substances at each additional physical location of the business or professional practice.

(9) A pharmacist shall maintain 1 controlled substance license in this state to dispense from any licensed pharmacy in this state.

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

Rule 35. (1) An individual who is applying for a controlled substance license or who is licensed to prescribe or dispense controlled substances ~~pursuant to~~**under** section 7303 of the code, MCL 333.7303, shall complete a 1-time training in opioids and controlled substances awareness that meets the following standards:

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

(i) Use of opioids and other controlled substances.

(ii) Integration of treatments.

(iii) Alternative treatments for pain management.

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

(v) The stigma of addiction.

(vi) Utilizing the MAPS.

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

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

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

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

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

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

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

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

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) A prescriber or dispenser shall ~~not~~ delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with subrules (1) and (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, an individual shall provide an acceptable proof of completion of training, including ~~either~~**1** of the following:

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

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

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

(a) A licensee who is renewing ~~his or her~~**a** controlled substance license shall complete the controlled substance training by the end of the first renewal cycle that begins after January 4, 2019.

(b) Other than a license renewal under subdivision (a) of this subrule, beginning September 1, 2019, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training.

(5) Beginning December 31, 2021, an individual, other than a physician's assistant, who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as allowed by the code, shall complete the controlled substance training required by subrule (1) of this rule.

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

R 338.3137 ~~Eliminate drug treatment program prescriber license requirement.~~
Rescinded.

~~Rule 37. The drug treatment program prescriber license is eliminated.~~

PART 4. SECURITY

R 338.3141 Thefts and diversions.

Rule 41. (1) An applicant or licensee shall provide effective controls against theft and diversion of controlled substances.

(2) A licensee shall confirm that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Within 15 days of completion of an investigation regarding a suspected theft or significant loss of a controlled substance, a licensee shall notify the department of the suspected theft or significant loss of a controlled substance and submit a copy of the DEA theft and loss report form 106, or equivalent document, to the department, whether or not the controlled substance is recovered or the responsible ~~person~~**individual** is identified and action is taken against ~~him or her~~**the responsible individual**, and whether or not it is also reported to the DEA.

(4) A licensee shall use all of the following criteria to determine if the loss in subrule (3) of this rule is significant:

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

(b) The specific controlled substance lost.

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

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

(e) Whether the specific controlled substance is a likely candidate for diversion.

(f) Local trends and other indicators of the diversion potential of the missing controlled substance.

R 338.3143 Storage of controlled substances.

Rule 43. (1) A licensee shall store controlled substances that are listed in schedule 1 in a securely locked, substantially constructed cabinet that is anchored to a wall or the floor.

(2) A licensee shall store controlled substances that are listed in schedules 2, 3, 4, and 5 in a securely locked, substantially constructed cabinet, room, or cart. However, in a pharmacy, the controlled substances may be dispersed throughout the stock of

~~noncontrolled~~**non-controlled** substances in a manner to obstruct the theft or diversion of controlled substances.

R 338.3145 Employees; disqualification.

Rule 45. (1) An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity who is licensed by the department ~~pursuant to~~**under** section 7303 of the code, MCL 333.7303**,** or section 17748 of the code, MCL 333.17748, shall not employ or utilize, with or without compensation, or allow the following individuals access to controlled substances:

(a) An individual who the licensee knows, or should reasonably know, to be a substance abuser as defined in section 16106a of the code, MCL 333.16106a. This subdivision does not apply to a licensee enrolled in the health professional recovery program under a current monitoring agreement.

(b) An individual whose controlled substance license is suspended, revoked, or denied.

(c) An individual whose license issued by this state or another state is under suspension or revoked for a violation that involves controlled substances.

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

(2) A licensee shall not delegate, ~~pursuant to~~**under** section 16215 of the code, MCL 333.16215, to a licensed or unlicensed individual unless the delegation complies with this rule.

PART 5. RECORDS

R 338.3151 Inventories.

Rule 51. (1) An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity licensed to manufacture, distribute, prescribe, or dispense controlled substances shall annually perform and maintain a complete and accurate inventory of all stocks of controlled substances in the possession and control of the licensee.

(2) The inventory must contain a complete and accurate record of all controlled substances in the possession or control of the licensee on the date the inventory is taken as follows:

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

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

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

(4) A licensee shall indicate on the inventory record whether the inventory was taken at the opening or closing of the day that the inventory is taken.

(5) A licensee shall maintain the inventory in a written, typewritten, or printed form at the licensed location. The inventory taken by use of an oral recording device must be promptly transcribed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Name of the patient.

(ii) Name and strength of the controlled substance.

(iii) Quantity of the controlled substance.

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

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

~~(g)~~**(d)** Except in medical institutions, a licensee shall sequentially number and maintain in chronological order the patients' original prescriptions as follows:

(i) A licensee shall maintain a separate file for dispensed substances listed in schedule 2.

(ii) A licensee shall maintain a separate file for dispensed substances listed in schedules 3, 4, and 5.

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

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

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

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

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

(iv) Date the controlled substances were distributed.

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

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

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

R 338.3153a Medication orders for patients in medical institutions.

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

(a) The patient's name.

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

(c) The prescriber's signature.

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

(e) The date of the medication order.

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

(a) The oral order of the prescriber is committed to a written or electronic order in the patient chart by a nurse licensed under part 172 of the code, MCL 333.17201 to 333.17242, a physician's assistant licensed under part 170 of the code, MCL 333.17001 to 333.17097, or part 175 of the code, MCL 333.17501 to 333.17556, or a pharmacist licensed under part 177 of the code, MCL 333.17701 to 333.17780, who has communicated directly with the prescriber.

(b) The order states the name of the prescriber and the name of the nurse, physician's assistant, or pharmacist who received the verbal order.

(c) The order is forwarded to the pharmacy.

(d) The prescriber signs the original order at the next visit or within 7 days.

(3) A licensee shall preserve an original order for a period of 5 years ~~from~~**after** the patient discharge date and the original order must be readily retrievable. After 2 years, a licensee may make an electronic duplicate of the original order ~~which~~**that** becomes the original order. If a licensee maintains patient records electronically, then a printed copy must be immediately available for a current inpatient and within 48 hours ~~upon~~**on** request of an authorized agent of the board for ~~any~~**a** patient **discharged in the last** ~~of the previous~~ 5 years.

R 338.3154 Medication records in medical institutions.

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

(2) Medication records are required for all controlled substances listed in schedules 2, 3, 4, and 5. At a minimum, these records must include all of the following information:

(a) The number of doses of controlled substances purchased.

(b) The number of doses dispensed to individual patients or distributed to nursing stations or both.

(c) The number of doses administered.

(d) The number of doses dispensed, but not administered, to the patient.

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

(a) Medication records for those controlled substances in schedules 2, 3, 4, and 5 must be maintained.

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

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

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

(ii) The quantity of the substance.

(iii) The date of delivery.

(iv) The location of the nursing unit.

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

(vi) Name of distributing pharmacist.

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

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

(i) The name of the substance.

(ii) The dose administered.

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

(iv) The name of the patient.

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

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

(4) A controlled substance that is maintained at a nursing unit must be stored in a securely locked cabinet or medication cart that is accessible only to an individual who is responsible for the administration or distribution of the medication.

(5) If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:

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

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

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

(d) The contents of the automated device.

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

(i) Use of monitors that alert the user ~~when~~**if** the wrong medication is filled or removed for administration to a patient.

(ii) Use of security monitors that include an alert for unauthorized access, patients not in the system, system security breaches, and controlled substance audits.

(iii) Corrective measures to address issues and errors identified in the internal quality assurance program.

(f) The policy and procedure for system operation that includes all of the following:

(i) Safety.

(ii) Security systems and procedures that include prevention of unauthorized access or use and comply with federal and state regulations.

(iii) Accuracy.

(iv) Patient confidentiality.

(v) Access.

(vi) Type of controlled substances.

(vii) Data retention or archival.

(viii) Definitions.

(ix) Downtime procedures.

(x) Emergency procedures.

(xi) Operator inspections.

(xii) Installation requirements.

(xiii) Maintenance.

(xiv) Medication security.

(xv) Medication inventory.

(xvi) Staff education and training.

(xvii) System set-up and malfunction.

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

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

following situations where a pharmacist shall review the orders and authorize ~~any~~ further dispensing within 48 hours:

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

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

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

(g) The automated device must maintain transaction data that includes all activity regarding access to the contents of the automated device.

(h) The pharmacy responsible for the automated device shall maintain records related to access to the automated device. The records must be readily retrievable and must include all of the following information:

(i) The unique identity of the device.

(ii) Identification of the individual accessing the automated device.

(iii) The type of transaction.

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

(v) The name of the patient.

(vi) The identification of the pharmacist checking for the accuracy of the medications to be stocked or restocked in the automated device.

(vii) ~~Any other information~~**Information** the pharmacist considers necessary.

(i) For medication removed from the automated device for on-site patient administration, the automated device must document all of the following information:

(i) The name of the patient.

(ii) The date and time medication was removed from the automated device.

(iii) The name, initials, or other unique identifier of the individual removing the drug.

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

(j) If the pharmacist delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another a board-approved error prevention technology.

(k) The automated device must provide a mechanism for securing and accounting for controlled substances removed from the automated device return bin. Controlled substances may not be returned directly to the automated device for immediate reissue or reuse. Controlled substances removed from the automated device may not be reused or reissued, except as indicated in R 338.486(7).

(l) The automated device must provide a mechanism for securing and accounting for wasted or discarded medications.

(6) An individual who is responsible for administering a controlled substance or a portion thereof shall record the quantity, disposition and an explanation of the destruction of the controlled substance on the proper accountability record. If the institution has a policy that reflects current practice standards and delineates the method of destruction, an explanation would only be required if policy was not followed.

PART 6. DISPENSING AND ADMINISTERING CONTROLLED SUBSTANCE PRESCRIPTIONS

R 338.3161 Controlled substance prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance must be dated and signed by the prescriber, ~~when~~**if** issued, and contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's DEA registration number, preprinted, stamped, typed, or manually printed name, address, **and** telephone number or pager number~~, and professional designation~~.

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

(d) The quantity prescribed. For a paper prescription received in writing, the prescription must contain the quantity in both written and numerical terms. A paper prescription **complies if it** ~~must contain~~**contains** preprinted numbers representative of the quantity next to a box or line that the prescriber may check.

(e) The directions for use.

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

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

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

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

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

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

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

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

(2) ~~Pursuant to~~**Under** Section 16204e of the code, MCL 333.16204e, a licensed prescriber may prescribe a controlled substance listed in schedules 2 to 5 without first

establishing the bona fide prescriber-patient relationship required under Section 7303a of the code, MCL 333.7303a, in the following situations:

(a) The prescriber is providing on-call coverage or cross-coverage for another prescriber who is not available and has established a bona fide prescriber-patient relationship with the patient for whom the on-call or covering prescriber is prescribing a controlled substance, the prescriber, or an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, reviews the patient's relevant medical or clinical records, medical history, and ~~any~~ change in medical condition, and provides documentation in the patient's medical record ~~pursuant to~~**consistent with** medically accepted standards of care.

(b)The prescriber is following or modifying the orders of a prescriber who has established a bona fide prescriber-patient relationship with a hospital in-patient or nursing care facility resident and provides documentation in the patient's medical record ~~pursuant to~~**consistent with** medically accepted standards of care.

(c) The prescriber is prescribing for a patient that has been admitted to a licensed nursing care facility, completes the tasks identified in subrule (2)(a) and (2)(b) of this rule in compliance with R 325.45377, as applicable, and provides documentation in the patient's medical record ~~pursuant to~~**consistent 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~~**are** performed by an individual licensed under article 15 of the code, MCL 333.16101 to 333.18838, and the prescriber provides documentation in the patient's medical record ~~pursuant to~~**consistent with** medically accepted standards of care.

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

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

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

(2) A pharmacist shall require positive identification of individuals to whom controlled substances are dispensed or delivered ~~when~~**if** the individual is not known to the pharmacist or pharmacy employees except ~~when~~**if** positive identification is not available and a pharmacist, who in exercising ~~his or her~~ professional judgment, determines that a delay in dispensing the controlled substance may be detrimental to a patient.

(3) Subrule (2) of this rule does not exempt a pharmacist from the requirement to submit a patient identifier to the electronic system for monitoring controlled substances.

(4) The dispensing pharmacist and pharmacy are both responsible for complying with this rule.

(5) A pharmacist may dispense a controlled substance that is listed in schedules 3 to 5 and that is a prescription drug ~~pursuant to~~**under** ~~the provisions of~~ the FDCA of 1991, 21

USC 353, ~~only pursuant to~~**under** a prescription on a prescription form, an oral prescription of a practitioner, or a prescription that is electronically transmitted pursuant to R 338.3162a and that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained ~~pursuant to~~**under** an oral order.

(6) In addition to the requirements in section 17744 of the code, MCL 333.17744, if a prescriber's agent under delegation transmits an oral prescription for a controlled substance to a pharmacy all of the following ~~shall~~**must** be recorded on the prescription generated at the pharmacy:

(a) The information required by R 338.3161.

(b) The transmitting agent's identity.

(c) The individual who received the prescription at the pharmacy.

(7) Only a prescription that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.

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

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

(a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient.

(b) The electronically transmitted prescription includes all of the following information:

(i) The name and address of the prescriber.

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

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

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

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

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

(vii) All other information that must be contained in a prescription under R 338.3161.

(c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

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

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

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

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

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

(4) A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy ~~either~~**1** of the following requirements:

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

(b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and the prescriber meets 1 of the following:

(i) ~~The prescription is dispensed by a dispensing prescriber.~~

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

~~(iii)~~**(ii)** The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following:

(A) Prescribing fewer than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the ~~Federal Centers for Medicare and Medicaid Services~~**CMS** waiver for electronic transmission of prescriptions for controlled substances, whichever is more.

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

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

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

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

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

Rule 62b. (1) Except as otherwise exempt under section 7333a of the code, MCL 333.7333a, a pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 of the code, MCL 333.17701 to 333.17780, who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a scheduled 2 to 5 controlled substance that has been dispensed:

(a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply:

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

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

(iii) If the medication being dispensed is for an animal, the patient identification number applies to the animal's owner, the client, that meets the requirements of R

338.3102(1)(f)(iv). If the animal's owner cannot be identified, zeroes must be entered as the identification number.

(b) The patient's name; client's name, including first name, middle name, or middle initial, if available; and last name.

(c) The patient's or client's address, including street, city, state, and zip code.

(d) The patient's or client's phone number.

(e) The patient's or client's gender.

(f) The patient's or client's date of birth.

(g) The species code, as specified by ASAP.

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

(i) The NDC of the controlled substance dispensed.

(j) The date of issue of the prescription.

(k) The date ~~of dispensing~~**the prescription is filled**.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

(o) The prescription number assigned by the dispenser.

(p) The prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription.

(q) The prescription payment type. Cash discount cards are considered cash transactions.

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

(s) The patient's or client's location code ~~when~~**if** receiving ~~pharmacy services~~**direct or indirect patient care services association with the practice of pharmacy, as defined in section 17707 of the code, MCL 333.17707**, as specified by ASAP.

(t) The DEA registration number of the prescriber and the dispensing pharmacy.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient, ~~or~~ a patient's representative, or veterinarian's client is correct.

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

(4) As used in this rule, the term "patient" refers to an individual, not an animal.

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

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

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

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and who does not have an automated record-keeping system capable of

producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request ~~shall~~**must** be made in writing to the department.

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

R 338.3162d Required reporting of prescription data; error reporting.

Rule 62d. (1) A pharmacist, pharmacy, dispensing prescriber, or veterinarian shall report all scheduled 2 to 5 controlled substances dispensed.

(2) The licensee shall forward the data required by R 338.3162b by on-line transmission, computer diskette, compact disk, or other approved medium, as specified in R 338.3162c to the department or the department's contractor, on a daily basis, by the end of the next business day and include the data for all controlled substances dispensed since the previous transmission or report.

(3) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, shall mail or deliver the information to a location specified by the department or the department's contractor not later than 7 calendar days after the date that the controlled substance has been dispensed, and include the data for all controlled substances dispensed since the previous transmission or report.

(4) The department or the department's contractor shall notify a pharmacist, pharmacy, dispensing prescriber, or veterinarian of an error in data reporting. **If a pharmacist, pharmacy, dispensing prescriber, or veterinarian receives** ~~Upon receiving~~ notification of an error in data reporting, **the** ~~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~~**after** being notified of the error.

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as required, is subject to the penalty provisions in section 16221, 17741, or 17768 of the code, MCL 333.16221, 333.17741, or 333.17768, in article 15 of the code, MCL 333.16101 to 333.18838.

R 338.3163 Individual with substance use disorder; prescribing, dispensing, and administering controlled substance. Reviewing relevance and MAT Act.

Rule 63. (1) A practitioner within ~~his or her~~**the practitioner's** scope of practice, may either prescribe, dispense, or administer a controlled substance to an individual with substance use disorder for the purpose of maintenance or detoxification treatment ~~pursuant to~~**under** ~~any of~~ the following situations:

(a) A practitioner acting ~~pursuant to~~**under** federal law or regulations to conduct the drug treatment of an individual with substance use disorder may prescribe, dispense, and administer a controlled substance for the purpose of legitimate treatment of the individual

with substance use disorder. A prescription may only be issued for a schedule 3 through 5 substance.

(b) A practitioner may administer or dispense a controlled substance approved by the FDA specifically for use in maintenance or detoxification treatment directly to an individual with substance use disorder who is participating in a program.

(c) A practitioner may administer a controlled substance approved by the FDA specifically for use in maintenance or detoxification treatment directly to an individual with substance use disorder who is experiencing acute withdrawal symptoms and administration of a controlled substance is necessary while the practitioner is arranging referral for treatment. The following requirements must be followed:

(i) Not more than 1 day's supply of medication may be administered or directly dispensed to the individual with drug addiction or dependence.

(ii) The emergency treatment may be carried out for not more than 3 consecutive days and may not be renewed or extended.

(2) Notwithstanding subrule (1) of this rule, a practitioner within the scope of ~~his or her~~**the practitioner's** practice, may administer or dispense a controlled substance in a hospital or similar setting to an individual with substance use disorder consistent with both of the following:

(a) The controlled substance is administered or dispensed to continue maintenance or detoxification treatment as an adjunct to medical or surgical treatment of conditions other than addiction.

(b) The controlled substance is administered or dispensed to relieve intractable pain for which no relief or cure is possible, or none has been found after reasonable efforts.

(3) As use in this rule:

(a) “Practitioner” means the term **as** defined in section 7109 of the code, MCL 333.7109.

(b) “Program” means the term **as** defined in section 260 of the mental health code, 1974 PA 258, MCL 330.1260.

(c) “Substance use disorder” means that term as defined in section 100d of the mental health code, 1974 PA 258, MCL 330.1100d.

R 338.3164 Emergency dispensing of schedule 2 substances; oral prescriptions.

Rule 64. A pharmacist may dispense a controlled substance listed in schedule 2 in an emergency ~~in which~~**if** all ~~of~~ the following conditions are met:

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

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

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

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

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

(b) The pharmacist shall immediately put the prescription in writing, which contains the information that must be contained in a prescription under R 338.3161, except for the prescriber's signature.

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

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

Rule 65. (1) ~~Within 7 days after~~**After** authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall comply with all of the following **within 7 days**:

(a) The prescriber shall deliver to the dispensing pharmacist a written prescription **postmarked 7 days before the date the prescription was dispensed,** or electronically transmit the prescription ~~pursuant to~~**under** R 338.3162a.

(b) The prescriber shall include on the prescription both "Authorization for Emergency Dispensing" and the date of the oral order.

(2) A pharmacist that has dispensed a prescription on an emergency oral prescription shall comply with all of the following:

(a) The dispensing pharmacist shall reduce the oral prescription to writing.

(b) ~~Upon receipt of the prescription, the~~ **After the** dispensing pharmacist **receives the prescription the pharmacist** shall attach the prescription to the oral order ~~which~~**that** was earlier reduced to writing.

(c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** either a written prescription or a prescription transmitted electronically.

(3) The failure of the pharmacy to notify the department if the prescriber fails to deliver a prescription ~~pursuant to~~**under** subrule (1) of this rule voids the authority conferred by this rule.

R 338.3166 Partial dispensing of controlled substances.

Rule 66. (1) A pharmacist may partially dispense a controlled substance listed in schedule 2 in conformance with the following:

(a) The pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription.

(b) The pharmacist makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record.

(c) The pharmacist may dispense the remainder of the prescription within 72 hours after the first partial dispensing.

(d) If the remainder of the prescription is not or cannot be dispensed within the 72 hours, the pharmacist shall notify the prescriber.

(e) The pharmacist shall not dispense ~~any~~**an** additional quantity **of the drug** beyond 72 hours without a new prescription.

(f) The pharmacy ~~must~~**shall** have the balance of the prescription ready for dispensing before the 72-hour limit, but the patient is not required to pick up the balance of the prescription within that 72-hour limit.

(2) A pharmacist may partially dispense a prescription for a controlled substance in schedule 2 at the request of the patient or the prescribing practitioner in conformance with the following:

(a) The prescription is written and filled ~~pursuant to~~**under** the CSA and DEA regulations and state law.

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

(c) The remaining portions of a partially filled prescription in schedule 2, if filled, ~~shall~~**must** be filled not later than 30 days after the date ~~on which~~ the prescription was written.

(d) For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(i) Date of the partial filling.

(ii) Quantity dispensed.

(iii) Remaining quantity that may be dispensed.

(iv) Identification of the dispensing pharmacist.

(3) A pharmacist may partially dispense, including individual dosage units, a prescription for a schedule 2 controlled substance that is written for a patient in a long-term care facility or for a patient with a medical diagnosis that documents a terminal illness in conformance with all of the following:

(a) For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(i) Date of the partial filling.

(ii) Quantity dispensed.

(iii) Remaining quantity authorized to be dispensed.

(iv) Identification of the dispensing pharmacist.

(b) The total quantity of schedule 2 controlled substances dispensed in all partial fillings may not be more than the total quantity prescribed.

(c) Prescriptions are valid for a period of not more than 60 days ~~from~~**after** the issue date unless terminated at an earlier date by the discontinuance of medication.

(d) A pharmacist shall record on the prescription whether the patient is terminally ill or is a long-term care facility patient.

(4) A pharmacy may partially fill a prescription for a schedule 3, 4, or 5 controlled substance if all of the following provisions are met:

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

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

(c) No dispensing occurs after 6 months ~~from~~**after** the date the prescription was issued for schedules 3, 4, and 5.

R 338.3167 Dispensing schedule 5 substances without prescriptions.

Rule 67. (1) A pharmacist may, without a prescription, dispense a controlled substance listed in schedule 5 that is not a prescription medication as determined under the FDCA, 21 USC 301 to 392, if all of the following provisions are met:

(a) The dispensing pharmacist determines the controlled substance is intended to be used for a medical purpose.

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

(c) The purchaser is not younger than 18 years of age.

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

(2) If a pharmacist dispenses a controlled substance listed in schedule 5 without a prescription, then ~~he or she~~**the pharmacist** shall affix **a label** to the container ~~in which~~**that holds** the substance ~~is dispensed~~**that includes all the following:**

(i) The ~~a label that shows the~~ date **the controlled substance was dispensed.** ~~,~~

(ii) The ~~his or her~~ **pharmacist** name**.** ~~, and the~~

(iii) The name and address of the ~~place of practice~~**pharmacy** where the substance is dispensed.

(3) The pharmacist shall maintain a record of the dispensing without a prescription of controlled substances listed in schedule 5 with the following requirements:

(a) The record must be ~~kept~~**maintained** for 5 years ~~from~~**after** the date of dispensing. After 2 years, an electronic duplicate of the original order may be made which becomes the original record.

(b) The record must be immediately retrievable and may be maintained in the same manner as required for schedule 5 prescription medication.

(c) The record must contain all of the following information:

(i) The name and address of the patient.

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

(iii) The name and quantity of substance purchased.

(iv) The date purchased.

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

(vi) The medical purpose ~~for which~~**of** the medication ~~is being used~~ as determined by the pharmacist.

R 338.3168 Refilling of prescriptions.

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

(2) A prescription for a controlled substance listed in schedules 3 and 4 may not be refilled more than 6 months after the prescription's date of issuance and may not be refilled more than 5 times. Renewal of the prescription must be consistent with the requirements for original prescriptions.

(3) A prescription for a controlled substance listed in schedule 5 may be refilled only as expressly authorized by the prescriber on the prescription up to 1 year; if no authorization is indicated, then the prescription may not be refilled.

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of ~~his or her~~**the prescriber's** professional practice may dispense, ~~or~~ administer, or delegate under direct supervision the administering of a controlled substance listed in schedules 2 to 5.

(2) A veterinarian, in the course of ~~his or her~~**the veterinarian's** professional practice may dispense, administer, or delegate the administering under direct supervision of a controlled substance listed in schedules 2 to 5 to an animal.

PART 7. DISTRIBUTIONS

R 338.3181 Distributions by dispensers.

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

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

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

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

(d) The total number of dosage units of all controlled substances distributed by the distributing dispenser during the 12-month period ~~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~~**the dispenser** ~~pursuant to~~**under** this rule ~~will be~~**are** more than 5% of the total number of dosage units of all controlled substances distributed and dispensed by ~~him or her~~**the dispenser** during the 12-month period, the dispenser shall obtain a license to distribute controlled substances.

R 338.3183 Distribution to suppliers.

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

(a) The date of the distribution.

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

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

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

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

R 338.3185 Discontinuances and transfers.

Rule 85. A licensee who wants to discontinue or transfer business activities or a professional practice altogether or only with respect to controlled substances ~~shall return his or her DEA registration and any unexecuted order forms in his or her possession to~~

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

R 338.3186 Use of order forms and invoices.

Rule 86. An order form must be used to distribute schedule 2 substances and an invoice must be used to distribute schedules 3 to 5 substances. The order form may be executed only by a practitioner who is licensed under article 7 of the code, MCL 333.7101 to 333.7545, to prescribe or dispense controlled substances.

~~PART 8. ADMINISTRATIVE AND DISCIPLINARY PROCEDURE~~