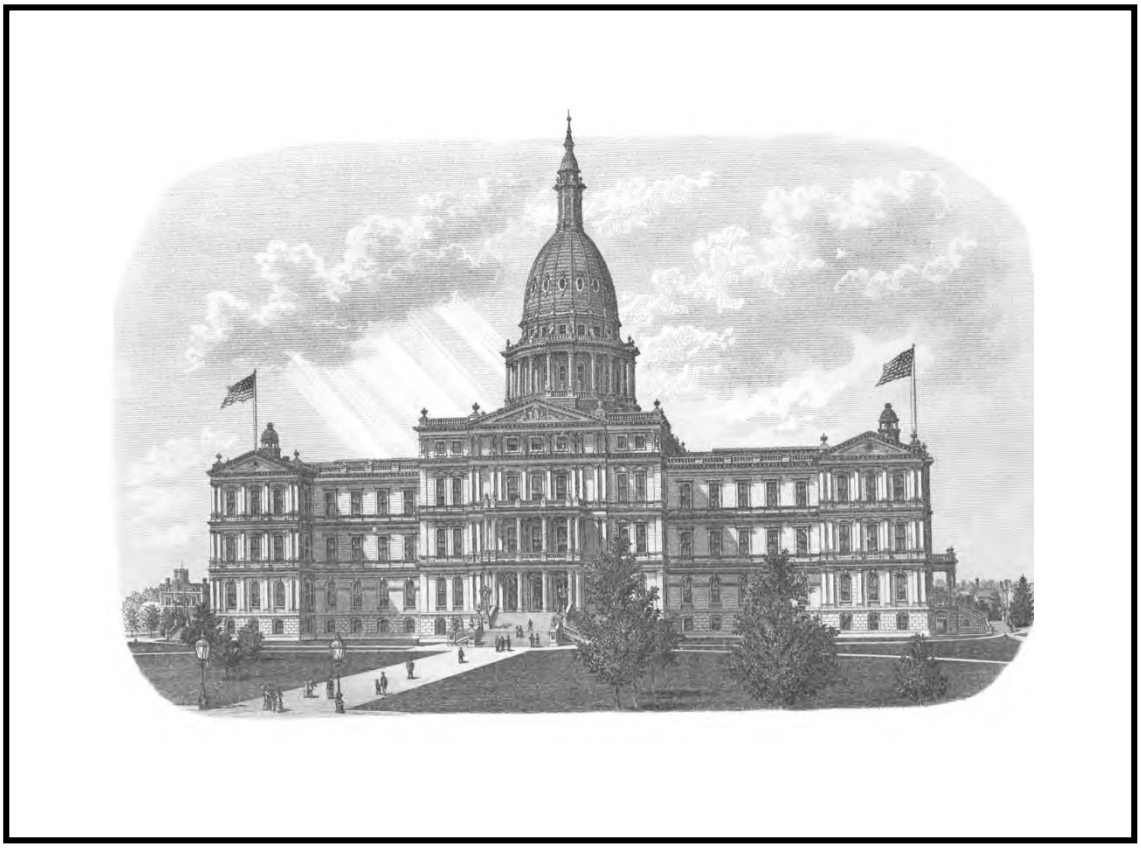
Michigan Register

Issue No. 8 – 2024 (Published May 15, 2024)



GRAPHIC IMAGES IN THE

MICHIGAN REGISTER

COVER DRAWING

Michigan State Capitol:

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

(Michigan State Archives)

PAGE GRAPHICS

Capitol Dome:

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

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

(Michigan State Archives)

East Elevation of the Michigan State Capitol:

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

(Michigan Capitol Committee)

Michigan Register

Published pursuant to § 24.208 of
The Michigan Compiled Laws

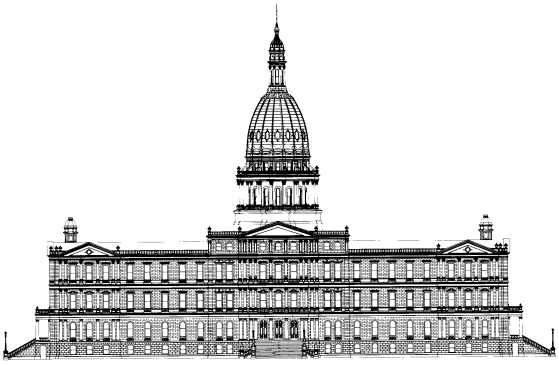
Issue No. 8— 2024
(This issue, published May 15, 2024, contains
documents filed from April 1, 2023 to May 1, 2024)

Compiled and Published by the
Michigan Office of Administrative Hearings and Rules

Michigan Register (ISSN 0892-3124). Published twice per month, with a cumulative index, by the Michigan Office of Administrative Hearings and Rules, pursuant to §24.208 of the Michigan Compiled Laws. Subscription $400.00 per year, postpaid to points in the U.S. First class postage paid at Lansing, Michigan. Direct all mail concerning subscriptions to Michigan Office of Administrative Hearings and Rules, Ottawa Building – Second Floor, 611 W. Ottawa Street, Lansing, MI 48909.

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

Gretchen Whitmer, Governor



Garlin Gilchrist, Lieutenant Governor

PREFACE

PUBLICATION AND CONTENTS OF THE MICHIGAN REGISTER

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

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

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

Sec. 8.

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

(a) Executive orders and executive reorganization orders.

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

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

(d) Proposed administrative rules.

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

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

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

(h) Notice of proposed and adopted agency guidelines.

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

(j) Attorney general opinions.

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

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

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

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

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

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

Sec. 203.

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

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

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

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

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

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

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

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

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

CITATION TO THE MICHIGAN REGISTER

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

CLOSING DATES AND PUBLICATION SCHEDULE

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

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

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

RELATIONSHIP TO THE MICHIGAN ADMINISTRATIVE CODE

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

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

SUBSCRIPTIONS AND DISTRIBUTION

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

INTERNET ACCESS

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

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

Executive Director,
Michigan Office of Administrative Hearings and Rules

2024 PUBLICATION SCHEDULE

Issue No.	Closing Date for Filing or Submission Of Documents (5 p.m.)	Publication Date
1	January 1	February 1
2	January 15	February 15
3	February 1	March 1
4	February 15	March 15
5	March 1	April 1
6	March 15	April 15
7	April 1	May 1
8	April 15	May 15
9	May 1	June 1
10	May 15	June 15
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22	November 15	December 15
23	December 1	January 1
24	December 15	January 15

CONTENTS

PROPOSED ADMINISTRATIVE RULES, NOTICES OF PUBLIC HEARINGS

MCL 24.242(3) states in part:

"… the agency shall submit a copy of the notice of public hearing to the Office of Regulatory Reform for publication in the Michigan register. An agency's notice shall be published in the Michigan register before the public hearing and the agency shall file a copy of the notice of public hearing with the Office of Regulatory Reform."

MCL 24.208 states in part:

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

* * *

(d) Proposed administrative rules.

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

PROPOSED ADMINISTRATIVE RULES

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

(By authority conferred on the director of the department of licensing and regulatory affairs **and board of pharmacy** by sections 16145~~(3)~~, 17701, and 17775 of **the public health code,** 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.

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

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

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

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

~~(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.~~

(e) “FDA” means the Federal Food and Drug Administration.

(~~g~~**f**) “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.~~

(g) “Original sealed and tamper-evident packaging” means unopened, tamper-evident packaging, as that term is defined in USP, Chapter 659, “Packaging and Storage Requirements,” including, but not limited to, an unopened unit-dose container or a multiple-dose container, as those terms are defined in USP, Chapter 659, “Packaging and Storage Requirements,” and immediate, secondary, and tertiary packaging.

(~~i~~**h**) "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~~**i**) “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~~**j)** “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.

(k) “USP” means the United States Pharmacopeia, published by the United States Pharmacopeial Convention.

(l) “USP-NF” means the United States Pharmacopeia National Formulary.

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

(2) Terms defined in the code have the same meaning when used in these rules unless otherwise defined 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 to 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~~ **licensing** 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 **and charitable clinic pharmacy licensed under article 15 of the code, MCL 333.16101 to 333.18838,** or charitable clinic **licensed under article 17 of the code, MCL 333.20101 to 333.22260.**~~, 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(2)(c) 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 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 **described** ~~defined~~ in ~~article 7 of the code~~ **R 338.3111**~~ 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 FDA'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~~ **This subdivision does not apply to** drugs donated directly from a drug manufacturer **or an eligible facility that 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 that 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 **Standards and procedures for inspecting** ~~Donated~~ **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 **and the lot number if the donation is received from an outsourcing facility.** 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, **or misbranding** and there is no reason to believe that the drug is adulterated **or misbranded**.

(f) The packaging does not have ~~any~~ physical signs of tampering, deterioration, compromised integrity, **misbranding,** 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. This form must comply with R 338.3621a.** ~~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~~ **Before 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 **or misbranded**, 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. **This includes unused prescription drugs that met eligibility requirements for distribution upon receipt but were subsequently not dispensed to an eligible patient under the program.**

(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 that 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 federal or state law, or rule to the contrary, a participating pharmacy may repackage a donated prescription drug or medical supply as necessary for storage, dispensing, administration, or transfers pursuant to both of the following:

(a) Repackaged medicine must be labeled with the drug name, strength, and expiration date and must be stored in a separate designated area until inspected and initialed by a pharmacist.

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

(c) The expiration date must be no later than 1 year after the date the drug was repackaged.

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, resident donation form, eligible participant form, transfer form, destruction form;~~ **general** requirements.

Rule 21. ~~(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.~~

(~~6~~**1**) All forms required for participation in the program must be maintained ~~separate~~ **separately** 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 that 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 **Professional Licensing** ~~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.

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

Rule 21a. 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 is donating 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 is receiving 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.

(f) An attestation that the transaction complies with the requirements of the drug supply chain security act, Public Law 113-54, or is subject to a waiver, exemption, or exception by the FDA.

R 338.3621b Eligible participant form; requirements.

Rule 21b. The eligible participant form must include all of the following information before receiving the first donated prescription drug:

(a) An attestation from the eligible participant that includes both 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.

(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 of 1970, 15 USC 1471 to 1477.

R 338.3621c Transfer form; requirements.

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

(a) The following information for each prescription drug:

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

(ii) Name of the manufacturer ~~or~~ and National Drug Code (NDC) Number.

(iii) Quantity and strength of the drug.

(iv) The container size.

(v) The number of containers.

(vi) The product identifier.

(vii) Date the drug was donated.

(viii) The date of the shipment, if more than 24 hours after the date of the transaction.

(ix) 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) An attestation stating that "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" made by the pharmacist or facility manager who is responsible or the eligible facility or manufacturer.

(e) An attestation stating that this transaction complies with the requirements of the drug supply chain security act, Public Law 113-54, or is subject to a waiver, exemption, or exception by the FDA.

R 338.3621d Destruction form; requirements.

R 21d. 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 NDC number.

(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 ~~drugs~~ **drug**.

(~~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 ~~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)~~**(3)** The eligible participant shall not be charged a handling fee if the eligible participant is receiving a professional sample ~~which~~**that** is distributed to patients at the same charitable clinic ~~whom~~**who** 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 it has 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's~~ **clinic and** ~~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 person~~**an individual** a prescription drug or ~~any other~~ **another** medication that is ineligible for distribution under the program for destruction and disposal **in accordance with 21 CFR part 1317**.

(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 **for ineligible drugs**; requirements.

Rule 35. A participating pharmacy or charitable clinic shall utilize a collection device to collect prescription drugs and other medications that**, upon receipt,** 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 securely fastened to a permanent structure.**

(c) Is a tamper resistant, securely locked, substantially constructed container with a permanent outer container and a removable inner liner.

~~(b)~~**(d)** Is labeled ~~pursuant to~~ **consistent with** all applicable state and federal laws and regulations~~.~~ **and includes the following statements prominently displayed on the collection device, and also in another location near the collection device:**

(i) "Controlled substances cannot be accepted for destruction and disposal, unless allowed under federal law."

(ii) "Chemotherapeutic agents must not be placed in this collection device."

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

(f) 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 tamper resistant and is securely locked.~~

~~(f) Is securely fastened to 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 be posted as signage near the location of the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless permitted under federal law." and "Chemotherapeutic agents shall 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 to **collection device**; destruction of **ineligible** collected drugs.

Rule 37. (1) **For noncontrolled substances, the following rules of destruction must be followed:**

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

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

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

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

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

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

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

(2) For controlled substances, destruction procedures under federal law must be followed pursuant to 21 CFR 1317.95.

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 third party~~ **the individual who is** 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.

(3) If controlled substances are destroyed, the participant must complete the Drug Enforcement Agency Form 41 and keep it for 2 years in accordance with 21 USC 827.

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~~**rulemaking** process.

Rule 43. The department shall notify the director of the department of **health and** human services ~~and the director of the department of community health of an approved~~ **of a** request for ~~rule-making~~**rulemaking that is approved** under **section 39 of the administrative procedures act of 1969, 1969 PA 306,** MCL 24.239**,** for ~~rule promulgation affecting~~ **any proposed rulemaking that would affect** 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~~ **proposed rulemaking** to the department within 30 days ~~of~~ **after** receipt of notification of the approved request for ~~rule-making~~ **rulemaking**.

NOTICE OF PUBLIC HEARING

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Administrative Rules for Pharmacy – Program for Utilization of Unused Prescription Drugs
Rule Set 2022-62 LR

NOTICE OF PUBLIC HEARING
Monday, May 20, 2024
09:00 AM

Room UL-4
611 W. Ottawa St, Lansing, Michigan

The Department of Licensing and Regulatory Affairs will hold a public hearing to receive public comments on proposed changes to the Pharmacy – Program for Utilization of Unused Prescription Drugs rule set.

The proposed rules include the following modifications: update the rules; allow drugs that include a USP-recognized method to detect improper temperature variations in the donation packaging; after two years allow an electronic duplicate of an original record; update the requirements for donated prescription drugs; delete the form required by a resident of an eligible facility; allow forms similar to the department forms to be used by participants; allow a pharmacy to repackage donated medications; and modify the requirements for a handling fee.

By authority conferred on the director of the department of licensing and regulatory affairs and board of pharmacy sections 16145, 17701, and 17775 ofthe public health code, 1978 PA 368, MCL 333.16145, 333.17701, and 333.17775 and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011 -4, MCL 338.3501, 445.2001, 445.2011, and MCL 445.2030.

The proposed rules will take effect immediately after filing with the Secretary of State. The proposed rules are published on the State of Michigan's website at www.michigan.gov/ARD and in the 5/15/2024 issue of the Michigan Register. Copies of these proposed rules may also be obtained by mail or electronic mail at the following email address: BPL-BoardSupport@michigan.gov.

Comments on these proposed rules may be made at the hearing, by mail, or by electronic mail at the following addresses until 5/20/2024 at 05:00PM.

Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing– Boards and Committees, Attention: Departmental Specialist

P.O. Box 30670, Lansing, MI 48909-8170

BPL-BoardSupport@michigan.gov

The public hearing will be conducted in compliance with the 1990 Americans with Disabilities Act. If the hearing is held at a physical location, the building will be accessible with handicap parking available. Anyone needing assistance to take part in the hearing due to disability may call 711- to make arrangements.

PROPOSED ADMINISTRATIVE RULES

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

INSURANCE

TERM AND UNIVERSAL LIFE INSURANCE RESERVE FINANCING

Filed with the secretary of state on

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

(By authority conferred on the director of the department of insurance and financial services by sections 210 and 1106 of the insurance code of 1956, 1956 PA 218, MCL 500.210 and 500.1106, and Executive Reorganization Order No. 2013-1, MCL 550.991)

R 500.121, R 500.122, R 500.123, R 500.124, R 500.125, R 500.126, R 500.127, and R 500.128 are added to the Michigan Administrative Code, as follows:

R 500.121 Definitions.

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

(a) "Accounting practices and procedures manual" means the NAIC accounting practices and procedures manual described in section 1106(3)(c) of the act, MCL 500.1106.

(b) "Act" means the insurance code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.

(c) "Actuarial method" means the methodology used to determine the required level of primary security pursuant to R 500.126.

(d) "Covered policy" or "covered policies" means 1 or more policies of the following types that are not grandfathered policies, unless exempted from these rules under R 500.125:

(i) Life insurance policies with guaranteed nonlevel gross premiums, guaranteed nonlevel benefits, or both, except for flexible premium universal life insurance policies.

(ii) Flexible premium universal life insurance policies with provisions that enable a policyholder to keep a policy in force over a secondary guarantee period.

(e) "Grandfathered policies" means policies of the types described in subdivision (d)(i) and (ii) of this subrule that were issued before January 1, 2015, and ceded, as of December 31, 2014, as part of a reinsurance treaty that would not have met an exemption under R 500.125 if that rule was effective.

(f) "Non-covered policies" means a policy or policies that are not covered policies, including grandfathered policies.

(g) "Primary security" means the following forms of security:

(i) Cash, to the extent that this form of security would meet the requirements described in section 1105 of the act, MCL 500.1105.

(ii) Securities listed by the Securities Valuation Office of the NAIC meeting the requirements of section 1105(b) of the act, MCL 500.1105, excluding the following:

(A) A synthetic letter of credit, contingent note, credit-linked note, or other similar security that operates in a manner similar to a letter of credit.

(B) Securities issued by the ceding insurer or any of its affiliates.

(iii) For security held in connection with funds withheld and modified coinsurance reinsurance treaties, the following:

(A) Commercial loans in good standing of CM3 quality and higher, as assigned by the NAIC and prescribed by the director.

(B) Policy loans.

(C) Derivatives acquired in the normal course and used to support and hedge liabilities pertaining to the actual risks in the policies ceded pursuant to the reinsurance treaty.

(h) "Other security" means any security that is not primary security and is acceptable to the director.

(i) "Required level of primary security" means the dollar amount determined by applying the actuarial method to the risks ceded with respect to covered policies, but not more than the total reserve ceded.

(j) "Risk-based capital" or "RBC" means the requirements described in section 410 of the act, MCL 500.410, as prescribed by the director.

(k) "Valuation manual" means the valuation manual described in section 1106(2) of the act, MCL 500.1106, as prescribed by the director pursuant to section 836b of the act, MCL 500.836b, in effect for the financial statement date on which credit for reinsurance is claimed.

(l) "VM-20" means the requirements for principle-based reserves for life products and all relevant definitions under the valuation manual.

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

R 500.122 Purpose.

Rule 2. (1) With respect to reserve financing arrangements pertaining to life insurance policies containing guaranteed nonlevel gross premiums, guaranteed nonlevel benefits, and universal life insurance policies with secondary guarantees, these rules ensure that funds consisting of primary security and other security are held by or on behalf of ceding insurers in the forms and amounts required under these rules.

(2) These rules create requirements in this state that support establishment of uniform, national standards governing the reserve financing arrangements described in subrule (1) of this rule.

(3) As used in this rule, reserve financing arrangements include reinsurance ceded for reserve financing purposes where some or all of the assets used to secure the reinsurance treaty, or to capitalize the reinsurer, meet 1 or more of the following:

(a) Are issued by the ceding insurer or its affiliates.

(b) Are not unconditionally available to satisfy the general account obligations of the ceding insurer.

(c) Create a reimbursement, indemnification, or another similar obligation of the ceding insurer or any if its affiliates, excluding a payment obligation under a derivative contract acquired in the normal course and used to support and hedge liabilities pertaining to the actual risks in the policies ceded pursuant to the reinsurance treaty.

R 500.123 Severability.

Rule 3. If any provision of this regulation is held invalid, the remainder is not affected.

R 500.124 Applicability.

Rule 4. (1) These rules apply to reinsurance treaties that cede liabilities pertaining to covered policies issued by a life insurance company domiciled in this state.

(2) These rules and R 500.1121 to R 500.1134 apply to reinsurance treaties described in subrule (1) of this rule. However, if there is a direct conflict between a provision of these rules and R 500.1121 to R 500.1134, the provision of these rules applies to the extent of the conflict.

(3) These rules apply to covered policies in force on or after the effective date of these rules.

R 500.125 Exemptions.

Rule 5. (1) These rules do not apply to the following situations:

(a) Reinsurance of any of the following:

(i) Policies that satisfy the criteria for the exemption described in section 838(7)(g) or (h) of the act, MCL 500.838, if issued before the later of the following dates:

(A) The effective date of these rules.

(B) The date the ceding insurer begins to apply the provisions of VM-20 to establish the ceded policies' statutory reserves, but not later than January 1, 2020.

(ii) Portions of policies that satisfy the criteria for the exemption described in section 838(7)(f) of the act, MCL 500.838, if issued before the later of the following dates:

(A) The effective date of these rules.

(B) The date the ceding insurer begins to apply the provisions of VM-20 to establish the ceded policies' statutory reserves, but not later than January 1, 2020.

(iii) Any universal life policy that meets all of the following requirements:

(A) The secondary guarantee period, if any, is 5 years or less.

(B) The specified premium for the secondary guarantee period is not less than the net level reserve premium for the secondary guarantee period based on the commissioners standard ordinary valuation tables and valuation interest rate applicable to the issue year of the policy.

(C) The initial surrender charge is not less than 100% of the first year annualized specified premium for the secondary guarantee period.

(iv) Credit life insurance.

(v) A variable life insurance policy that provides for life insurance, the amount or duration of which varies according to the investment experience of any separate account or accounts.

(vi) A group life insurance certificate unless the certificate provides for a stated or implied schedule of maximum gross premiums required in order to continue coverage in force for a period in excess of 1 year.

(b) Reinsurance ceded to an assuming insurer that meets the applicable requirements of section 1103(4) of the act, MCL 500.1103.

(c) Reinsurance ceded to an assuming insurer that meets the applicable requirements of section 1103(1) of the act, MCL 500.1103, with respect to reinsurance ceded to an assuming insurer that is licensed to transact insurance or reinsurance in this state, or of section 1103(2) or (3) of the act, MCL 500.1103. This subdivision does not apply unless both of the following are met with respect to the assuming insurer:

(i) Statutory financial statements are prepared in compliance with the accounting practices and procedures manual, without any departures from NAIC statutory accounting practices and procedures pertaining to the admissibility or valuation of assets or liabilities that increase the assuming insurer's reported surplus and are material enough that they need to be disclosed in the financial statement of the assuming insurer pursuant to statement of statutory accounting principles number 1.

(ii) Is not in a company action level event, regulatory action level event, authorized control level event, or mandatory control level event, as those terms are defined in RBC, when its risk-based calculation is calculated in accordance with the life risk-based capital report, including overview and instructions for companies, without deviation.

(d) Reinsurance ceded to an assuming insurer that meets the applicable requirements of section 1103(1) of the act, MCL 500.1103, with respect to reinsurance ceded to an assuming insurer that is licensed to transact insurance or reinsurance in this state, or of section 1103(2) or (3) of the act, MCL 500.1103. This subdivision does not apply unless all of the following are met with respect to the assuming insurer:

(i) Is not an affiliate, as that term is defined in section 115 of the act, MCL 500.115, of either of the following:

(A) The insurer ceding the business to the assuming insurer.

(B) An insurer that directly or indirectly ceded the business to that ceding insurer.

(ii) Prepares statutory financial statements in compliance with the accounting practices and procedures manual.

(iii) Is both of the following:

(A) Licensed or accredited in at least 10 states, including its state of domicile.

(B) Not licensed in a state as a captive, special purpose vehicle, special purpose financial captive, special purpose life reinsurance company, limited purpose subsidiary, or another similar licensing regime.

(iv) Is not, or would not be, below 500% of the authorized control level risk-based capital, as that term is defined in RBC, when its risk-based calculation is calculated in accordance with the life risk-based capital report, including overview and instructions for companies, without deviation or recognition of a departure from NAIC statutory accounting practices and procedures pertaining to the admission or valuation of assets or liabilities that increase the assuming insurer's reported surplus.

(e) Reinsurance ceded to an assuming insurer that meets the requirements of section 1106(3) of the act, MCL 500.1106.

(f) Reinsurance not otherwise exempt under subdivisions (a) to (e) of this subrule if the director, after consulting with the NAIC Financial Analysis Working Group or other group of regulators designated by the NAIC, as applicable, determines under all the facts and circumstances that all of the following apply:

(i) The risks are clearly outside of the purpose of these rules, as established in R 500.122.

(ii) The risks are included within the scope of these rules only as a technicality.

(iii) The application of these rules to those risks is not necessary to provide appropriate protection to policyholders.

(2) The director shall publicly disclose any decision made pursuant to subrule (1)(f) of this rule to exempt a reinsurance treaty from these rules. The disclosure must state the general basis for the decision, including a summary description of the treaty.

R 500.126 Actuarial method.

Rule 6. (1) The actuarial method used to establish the required level of primary security for each reinsurance treaty subject to these rules must be VM-20, applied on a treaty-by-treaty basis, including all relevant definitions, from the valuation manual. The actuarial method must be applied as follows:

(a) For covered policies described in R 500.121(1)(d)(i) the actuarial method is the greater of the deterministic reserve or the net premium reserve regardless of whether the criteria for exemption testing can be met. However, if the covered policies do not meet the requirements of the stochastic reserve exclusion test in the valuation manual, the actuarial method is the greatest of the deterministic reserve, the stochastic reserve, or the net premium reserve. In addition, if the covered policies are reinsured in a reinsurance treaty that also contains covered policies described in R 500.121(1)(d)(ii), the ceding insurer may elect to instead apply subdivision (b) of this subrule as the actuarial method for the entire reinsurance agreement. The actuarial method must comply with any requirements or restrictions that the valuation manual imposes when aggregating these policy types as used in principle-based reserve calculations when applying this subdivision or subdivision (b) of this subrule.

(b) For covered policies described in R 500.121(1)(d)(ii), the actuarial method is the greatest of the deterministic reserve, the stochastic reserve, or the net premium reserve regardless of whether the criteria for exemption testing can be met.

(c) Except as provided in subdivision (d) of this subrule, the actuarial method must be applied on a gross basis to all risks with respect to the covered policies as originally issued or assumed by the ceding insurer.

(d) If the reinsurance treaty cedes less than 100% of the risk, with respect to the covered policies, the required level of primary security may be reduced as follows:

(i) If a reinsurance treaty cedes only a quota share of some or all of the risks pertaining to the covered policies, the required level of primary security, and any adjustment under paragraph (iii) of this subdivision, may be reduced to a pro rata portion in accordance with the percentage of the risk ceded.

(ii) If the reinsurance treaty in a non-exempt arrangement cedes only the risks pertaining to a secondary guarantee, the required level of primary security may be reduced by an amount determined by applying the actuarial method on a gross basis to all risks, other than risks related to the secondary guarantee, pertaining to the covered policies. However, for covered policies for which the ceding insurer did not elect to apply the provisions of VM-20 to establish statutory reserves, the required level of primary security may be reduced by the statutory reserve retained by the ceding insurer on those covered policies, where the retained reserve of those covered policies is reflective of any reduction pursuant to the cession of mortality risk on a yearly renewable term basis in an exempt arrangement.

(iii) If a portion of the covered policy risk is ceded to another reinsurer on a yearly renewable term basis in an exempt arrangement, the required level of primary security may be reduced by the amount resulting by applying the actuarial method, including the reinsurance section of VM-20, to the portion of the covered policy risks ceded in the exempt arrangement. However, for covered policies issued before January 1, 2017, the adjustment must not exceed [c_x/ (2 * number of reinsurance premiums per year)] where "c_x" is calculated using the same mortality table used in calculating the Net Premium Reserve.

(iv) For any other treaty ceding a portion of risk to a different reinsurer, including, but not limited to, stop loss, excess of loss, and other non-proportional reinsurance treaties, there is no reduction in the required level of primary security.

(e) For the purposes of applying subdivision (d) of this subrule, any combination of subdivision (d)(i) to (iv) of this subrule may apply, in which case the adjustments to the required level of primary security must be done in the sequence that accurately reflects the portion of the risk ceded by the treaty. In addition, the ceding insurer shall document the rationale and steps taken to accomplish the adjustments to the required level of primary security due to the cession of less than 100% of the risk. The adjustments for other reinsurance must be made only with respect to reinsurance treaties entered into directly by the ceding insurer. The ceding insurer shall not make an adjustment as a result of a retrocession treaty entered into by the assuming insurers.

(f) Without exception, the required level of primary security resulting from applying the actuarial method must not exceed the amount of statutory reserves ceded.

(g) Without exception, if the ceding insurer cedes risks with respect to covered policies, including any riders, in more than 1 reinsurance treaty subject to these rules, the aggregate required level of primary security for those reinsurance treaties must not be less than the required level of primary security calculated using the actuarial method as if all risks ceded in those treaties were ceded in a single treaty subject to these rules.

(h) If a reinsurance treaty subject to these rules cedes risk on both covered policies and non-covered policies, credit for the ceded reserves must be determined as follows:

(i) The actuarial method must be used to determine the required level of primary security for the covered policies, and R 500.127 must be used to determine the reinsurance credit for the covered policy reserves.

(ii) Credit for the non-covered policy reserves must be granted only to the extent that security, in addition to the security held to satisfy the requirements of paragraph (i) of this subdivision, is held by or on behalf of the ceding insurer in accordance with sections 1103 and 1105 of the act, MCL 500.1103

and 500.1105. Any primary security used to meet the requirements of this paragraph must not be used to satisfy the required level of primary security for the covered policies.

(2) For the purposes of calculating the required level of primary security pursuant to the actuarial method and determining the amount of primary security and other security, as applicable, held by or on behalf of the ceding insurer, the following apply:

(a) For assets, including assets held in trust, that would be admitted under the accounting practices and procedures manual if they were held by the ceding insurer, the valuations must be determined according to statutory accounting procedures as if the assets were held in the ceding insurer's general account and without taking into consideration the effect of any prescribed or allowed practices.

(b) For all other assets, the valuations must be the valuations that were assigned to the assets for the purpose of determining the amount of reserve credit taken. In addition, the asset spread tables and asset default cost tables required by VM-20 must be included in the actuarial method if the director adopts the requirement following its adoption by the NAIC's Life Actuarial (A) Task Force no later than the December 31 that occurs on or immediately preceding the valuation date for which the required level of primary security is calculated. The tables of asset spreads and asset default costs must be incorporated into the actuarial method in the manner specified in VM-20.

R 500.127 Credit for reinsurance for covered policies; requirements; remediation.

Rule 7. (1) Subject to the exemptions described in R 500.125 and subrules (2) to (4) of this rule, credit for reinsurance must be allowed with respect to ceded liabilities pertaining to covered policies pursuant to section 1103 or 1105 of the act, MCL 500.1103 and 500.1105, only if, in addition to all other requirements imposed by law or regulation, all of the following requirements are met on a treaty-by-treaty basis:

(a) The ceding insurer's statutory policy reserves with respect to the covered policies are established in full and in accordance with the applicable requirements of the standard valuation law that is described in section 1106(2) of the act, MCL 500.1106, and adopted under chapter 8 of the act, MCL 500.808 to 500.842, including related regulation or rules and actuarial guidelines, and credit claimed for any reinsurance treaty subject to these rules does not exceed the proportionate share of those reserves ceded under the contract.

(b) The ceding insurer determines the required level of primary security with respect to each reinsurance treaty subject to these rules and provides support for its calculation as determined acceptable to the director.

(c) Funds consisting of primary security, in an amount at least equal to the required level of primary security, are held by or on behalf of the ceding insurer, as security under the reinsurance treaty within the meaning of section 1105 of the act, MCL 500.1105, on a funds withheld, trust, or modified coinsurance basis.

(d) Funds consisting of other security, in an amount at least equal to any portion of the statutory reserves as to which primary security is not held pursuant to subdivision (c) of this subrule, are held by or on behalf of the ceding insurer as security under the reinsurance treaty within the meaning of section 1105 of the act, MCL 500.1105.

(e) Any trust used to satisfy the requirements of this rule must comply with all of the conditions and qualifications of R 500.1123 and R 500.1133, subject to the following:

(i) Funds consisting of primary security or other security held in trust, for the purposes identified in R 500.126(2), must be valued according to the valuation rules set forth in R 500.126(2), as applicable.

(ii) There are no affiliate investment limitations with respect to any security held in the trust if the security is not needed to satisfy the requirements of subdivision (c) of this subrule.

(iii) The reinsurance treaty must prohibit withdrawals or substitutions of trust assets that would leave the fair market value of the primary security within the trust, when aggregated with primary security

outside the trust that is held by or on behalf of the ceding insurer in the manner required by subdivision (c) of this subrule, below 102% of the level required by subdivision (c) of this subrule at the time of the withdrawal or substitution.

(iv) The determination of reserve credit under R 500.1123(3) must be determined according to the valuation rules set forth in R 500.126(2), as applicable.

(f) The reinsurance treaty has been approved by the director.

(2) The requirements of subrule (1) of this rule must be satisfied as of the date that risks under covered policies are ceded, if that date is on or after the effective date of these rules, and on an ongoing basis afterward. With no exception, a ceding insurer shall not take or consent to any action or series of actions that would result in a deficiency under subrule (1)(c) or (d) of this rule with respect to any reinsurance treaty under which covered policies have been ceded, and if a ceding insurer becomes aware at any time that a deficiency described in this subrule exists, the ceding insurer shall use best efforts to arrange for the deficiency to be eliminated as expeditiously as possible.

(3) Before the due date of each quarterly or annual statement, each life insurance company that has ceded reinsurance within the scope of R 500.124 shall perform an analysis, on a treaty-by-treaty basis, to determine, as to each reinsurance treaty under which covered policies have been ceded, whether as of the end of the immediately preceding calendar quarter (the valuation date) the requirements of subrule (1)(c) and (d) of this rule were satisfied. The ceding insurer shall establish a liability equal to the excess of the credit for reinsurance taken over the amount of primary security actually held pursuant to subrule (1)(c) of this rule, unless either of the following apply:

(a) The requirements of subrule (1)(c) and (d) of this rule were fully satisfied as of the valuation date as to the reinsurance treaty.

(b) Any deficiency has been eliminated before the due date of the quarterly or annual statement to which the valuation date relates through the addition of primary security or other security, as applicable, in the amount and form as would have caused the requirements of subrule (1)(c) and (d) of this rule to be fully satisfied as of the valuation date.

(4) Subrule (3) of this rule does not allow a ceding company to maintain any deficiency under subrule (1)(c) and (d) of this rule for any period of time longer than is reasonably necessary to eliminate it.

R 500.128 Prohibition against avoidance.

Rule 8. An insurer that has covered policies applicable to these rules shall not take any action or series of actions or enter into any transaction or arrangement or series of transactions or arrangements, if the purpose is to avoid the requirements of these rules or to circumvent the purpose of these rules, as established in R 500.122.

NOTICE OF PUBLIC HEARING

Department of Insurance and Financial Services
Insurance
Administrative Rules for Term and Universal Life Insurance Reserve Financing
Rule Set 2023-64 IF

NOTICE OF PUBLIC HEARING
Tuesday, June 4, 2024
09:30 AM

Ottawa Building, Conference Room #6
611 West Ottawa Street, Lansing, Michigan 48933

The Department of Insurance and Financial Services will hold a public hearing to receive public comments on proposed changes to the Term and Universal Life Insurance Reserve Financing rule set.

The proposed rules govern reserve financing arrangements used by certain life insurers in reinsurance transactions to secure the reinsurance treaty or capitalize the reinsurer. The proposed rules ensure that funds backing these transactions are held in the appropriate form and level of security. The proposed rules would adopt Model Regulation #787 of the National Association of Insurance Commissioners.

By authority conferred on the Director of the Department of Insurance and Financial Services in Sections 210 and 1106 ofthe Insurance Code of 1956, 1956 PA 218, MCL 500.210 and 500.1106, and Executive Reorganization Order No. 2013-1, MCL 550.991.

The proposed rules will take effect immediately after filing with the Secretary of State. The proposed rules are published on the State of Michigan's website at www.michigan.gov/ARD and in the 5/15/2024 issue of the Michigan Register. Copies of these proposed rules may also be obtained by mail or electronic mail at the following email address: EstradaM1@michigan.gov.

Comments on these proposed rules may be made at the hearing, by mail, or by electronic mail at the following addresses until 6/4/2024 at 05:00PM.

Michele Estrada, Administrative Assistant to the Director of the Office of Appeals, Legal Research, and Market Regulation

Department of Insurance and Financial Services, Office of Appeals, Legal Research, and Market Regulation, P.O. Box 30220, Lansing, MI 48909-7720

EstradaM1@michigan.gov

The public hearing will be conducted in compliance with the 1990 Americans with Disabilities Act. If the hearing is held at a physical location, the building will be accessible with handicap parking available. Anyone needing assistance to take part in the hearing due to disability may call 517-284-8735 to make arrangements.

CUMULATIVE INDEX

LICENSING & REGULATORY AFFAIRS, DEPARTMENT OF
Correction:
Construction Codes - Part 7. Plumbing Code (2024-1)
Construction Code - Part 9A Mechanical Code (2024-1)

Acupuncture - General Rules (2024-4*)
Audiology – General Rules (2024-7*)
Carnival and Amusement Safety (2024-6)
Chiropractic – General Rules (2024-4*)
Construction Code - Part 4. Building Code (2024-4*)
Construction Codes - Part 5. Residential Code (2024-4*)
Construction Code - Part 10. Michigan Uniform Energy Code (2024-2*)
Construction Code - Part 10a. Michigan Energy Code (2024-2*)
Genetic Counseling - General Rules (2024-4)
Licensing of Health Facilities or Agencies (2024-6)
Medicine - General Rules (2024-6)
Nursing Home Administrators—General Rules (2024-5*)
Pharmacy-General Rules (2024-5)
Pharmacy – Program for Utilization of Unused Prescription Drugs (2024-8*)
Public Health Code – General Rules (2024-2*)
Rehabilitation Code (2024-4*)
Responsibilities of Providers of Basic Local Exchange Service that Cease to Provide the Service (2024-6)
Securities (2024-6*)

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NATURAL RESOURCES, DEPARTMENT OF
State Land Use Rules (2024-6)

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

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

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

MCL 24.208 states in part:

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

* * *

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

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

2024 Michigan Public Acts Table

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

April 30, 2024
Compiled through PA 39 of 2024

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

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

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

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

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

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PA No.	ENROLLED		I.E.* Yes/No	Governor Approved	Filed Date	Effective Date	SUBJECT
	HB	SB					
0039	4608		No	4/30/2024	4/30/2024	**	***Health occupations***; *dietitians and nutritionists*; licensure of dietitian nutritionists; provide for. ***(Rep. Laurie Pohutsky)***

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+ - Line item veto.
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