

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PROGRAM FOR UTILIZATION OF UNUSED PRESCRIPTION DRUGS

(By authority conferred on the director of the department of licensing and regulatory affairs and board of pharmacy by sections 16145, 17701, and 17775 of the 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 445.2030)

R 338.3601 Definitions.

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

(a) “Chemotherapeutic agent” means a chemical agent used for treating various forms of cancer generally by killing the cancer cells.

(b) “Code” means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(c) “Department” means the department of licensing and regulatory affairs.

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

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

(f) “Hazardous waste” means hazardous waste as that term is defined in R 299.9203.

(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.

(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.

(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.

(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.

(m) “Waste disposal facility” means a waste diversion center or disposal facility that 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.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

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 licensing standards, and shall hold an active, nonrestricted, license in this state.

(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, all the following:

(a) The name, address, 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.

(b) For a charitable clinic, evidence that the charitable clinic meets the requirements in 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 by providing written notice to the department on a form provided by the department. All of the following information must be included on the notice of withdrawal form:

(a) Name, address, telephone number, and license 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 shall no longer participate in the program.

(c) Date of withdrawal.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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 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.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3607 Ineligible drugs; controlled substances prohibited.

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

(a) Controlled substances, as described in R 338.3111.

(b) Expired prescription drugs.

(c) Drugs that may be dispensed only to a patient registered with the drug's manufacturer under the FDA's requirements.

(d) Drugs that have been outside of a health professional's control unless sanitation and security can be assured following inspection by a licensed pharmacist in accordance with R 338.3609.

(e) Compounded drugs.

(f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or the USP-NF. 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 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 must be documented and destroyed under the protocols currently used by the participating pharmacy.

(b) A destruction record must be created and maintained for a period of 5 years after destruction of a controlled substance. 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.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3609 Standards and procedures for inspecting 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 storage requirements.

(c) The packaging contains the 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 must be destroyed if there is a recall.

(d) The drug is not expired.

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

(f) The packaging does not have 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 if the prescription drugs are donated under the terms of the program.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3613 Rescinded.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3615 Transfer and shipment of donated drugs; requirements.

Rule 15. (1) 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.

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

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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

Rule 17. (1) 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.

(2) The participating pharmacy or charitable clinic shall store donated drugs under the manufacturer's guidelines or USP-NF guidelines. Donated drugs must be stored and maintained in a manner that distinguishes them physically or electronically from other non-donated inventory.

(3) If donated drugs are not inspected immediately upon receipt, a participating pharmacy or charitable clinic shall 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 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 unused 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 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 must be done 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 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, manufacturer, 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 into a vial, no later than 6 months after repackaged into a compliance blister packaging, or no later than 60 days after repackaged into a customized patient medication package in accordance with R 338.525 that is prepared by a pharmacist for a specific patient and contains 2 or more prescribed solid oral dosage forms.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

R 338.3619 Rescinded.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

R 338.3621 Forms; general requirements.

Rule 21. (1) All forms required for participation in the program must be maintained separately from other records for 5 years except for prescriptions dispensed under the program which must be filed with the pharmacy's other prescriptions. 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.

(2) The department shall make available all forms required by the program. The forms must be available at no cost from the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, 611 West Ottawa Street, Lansing, Michigan 48909 or on the department's website at <https://www.michigan.gov/lara/bureau-list/bpl/resources/special-programs/utilization-of-unused-prescription-drugs-program>. 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.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

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, if applicable.

(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) A statement that the unused medication is eligible for donation as defined by R 338.3605 and R 338.3607.

(d) The name, address, and telephone number of the participating pharmacy or charitable clinic that is receiving the donation.

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

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

(g) 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.

History: 2025 MR 11, Eff. May 7, 2025.

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.

History: 2025 MR 11, Eff. May 7, 2025.

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 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.

History: 2025 MR 11, Eff. May 7, 2025.

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.

History: 2025 MR 11, Eff. May 7, 2025.

R 338.3623 Rescinded.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3625 Dispensing donated prescription drugs; requirements.

Rule 25. (1) A participating pharmacy or charitable clinic shall dispense a donated prescription 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.

(2) The participating pharmacy or charitable clinic shall remove patient identifying information from the package before dispensing the drug.

(3) A participating pharmacy or charitable clinic shall not resell a donated prescription drug; however, a participating pharmacy or charitable clinic may collect a handling fee under R 338.3627.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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 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. Nothing shall prevent the participating pharmacy or charitable clinic from accepting coverage of any applicable fees from another party when eligible participants may be unable to cover the cost.

(2) A handling fee charged for a donated prescription drug dispensed through the program is not eligible for reimbursement under the medical assistance program.

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

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

R 338.3629 Donation to other participating pharmacy or charitable clinic.

Rule 29. A participating pharmacy or charitable clinic may donate prescription drugs that it has received under the program to other participating pharmacies or charitable clinics for use under the program. The participating pharmacy or charitable clinic donating the prescription drugs shall complete a transfer form required under R 338.3621c.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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 must include the name, address, and telephone number of the participating pharmacy or charitable clinic and the name of the responsible pharmacist.

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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

Rule 33. (1) Under section 17776 of the code, MCL 333.17776, a participating pharmacy or charitable clinic shall accept from an individual a prescription drug or another medication that is ineligible for distribution under the program for destruction and disposal in accordance with 21 CFR part 1317.

(2) Unless allowed by federal law, controlled substances 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 must not be mixed with other prescription drugs collected for disposal under the program. The chemotherapeutic agent must be mixed with the participating pharmacy's or charitable clinic's hazardous waste.

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

History: 2014 AACCS; 2025 MR 11, Eff. May 7, 2025.

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 the following 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 for 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.

(d) Is labeled 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."

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

(f) The contents of the collection device must not be viewable from the outside of the collection device and the size or capacity of the collection device must be clearly marked on the outside of the collection device.

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

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

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) An individual shall access a collection device utilizing a removable liner only for the following purposes:

(i) To remove the contents for safe, effective, and immediate transportation.

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

(iii) To immediately transfer the contents to a responsible individual for transportation to a waste disposal facility.

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

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

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

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

(d) The contents of the collection device must be destroyed 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.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

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

Rule 39. (1) A participating pharmacy or charitable clinic shall maintain a destruction and disposal log that includes all the following information:

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

(b) The 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 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 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.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

R 338.3641 Transportation.

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

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.

R 338.3643 Department of health and human services; inclusion in rulemaking process.

Rule 43. The department shall notify the director of the department of health and human services of a request for rulemaking that is approved under section 39 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.239, for any proposed rulemaking that would affect eligible facilities or mental health or substance abuse clients. The department of health and human services shall provide input regarding the proposed rulemaking to the department within 30 days after receipt of notification of the approved request for rulemaking.

History: 2014 AACs; 2025 MR 11, Eff. May 7, 2025.