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 by sections 16145(3), 17701, and 17775 of 1978 PA 368, MCL 333.16145(3), 333.17701, and 333.17775 and Executive Reorganization Order No. 2011-4, MCL 445.2030)

R 338.3601. Definitions.

Rule 1. As used in this part:

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

(c) "Code" means 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) "Department" means the department of licensing and regulatory affairs, bureau of health care services.

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

(i) Is a resident of this state.

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

(g) "Hazardous waste" means hazardous waste as 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.

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

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

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

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

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

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

(j) “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) “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.

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

History: 2014 AACS.

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

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

(2) Participation in the program is voluntary.

(3) A pharmacy or charitable clinic may elect to participate in the program 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 of the pharmacy or charitable clinic, 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).

(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 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 be included on the notice of withdrawal form:

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

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

(c) Date of withdrawal.

History: 2014 AACS.

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), 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 AACS.

R 338.3607. Ineligible drugs; controlled substances prohibited.

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

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

(b) Expired prescription drugs.

(c) Drugs that may be dispensed only to a patient registered with the drug's manufacturer under 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 shall not be donated or accepted as part of the program. Excluded from this restriction are drugs donated directly from a drug manufacturer.

(2) Controlled substances submitted for donation shall 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 be documented and destroyed pursuant to the protocols currently used by the pharmacy.

(b) A destruction record shall be created and maintained for a period of 5 years after destruction for any controlled substances destroyed.

History: 2014 AACS.

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

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

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(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 lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications shall be destroyed in the event of a recall.

(d) The drug has an expiration date that is more than 6 months after the date that the drug was donated.

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

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

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

History: 2014 AACS.

R 338.3611 Donated prescription drugs; eligible facility 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 AACS.

R 338.3613 Resident of eligible facility; donations permitted.

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.

History: 2014 AACS.

Courtesy of www.michigan.gov/orr

R 338.3615 Transfer and shipment of donated drugs; requirements.

Rule 15. (1) Prior to the initial 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) Donated drugs under the program shall be shipped from the eligible facility or manufacturer to the participating pharmacy or charitable clinic via common or contract carrier.

History: 2014 AACS.

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

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

(2) The participating pharmacy or charitable clinic shall store donated drugs pursuant to the manufacturer's guidelines or usp-nf guidelines. Donated drugs shall not be stored with non-donated inventory at any time.

(3) When donated drugs are not inspected immediately upon receipt, a participating pharmacy or charitable clinic shall quarantine the donated drugs separately from all dispensing stock until the donated 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 protocols currently established by the pharmacy or charitable clinic for the destruction of prescription drugs.

(5) A participating pharmacy or charitable clinic shall create and maintain a destruction and disposal record for donated 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.

(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 drugs destroyed. The destruction shall be done pursuant to 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 established drug recall procedures.

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History: 2014 AACS.

R 338.3619 Record keeping; inventory; requirements.

Rule 19. (1) A participating pharmacy or charitable clinic shall keep records in conformance 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.

History: 2014 AACS.

R 338.3621 Forms; eligible facility donation form, resident donation form, eligible participant form, transfer form, destruction form; 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.

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(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,

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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) All forms 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.

(7) The department shall make available all forms required by the program. The forms shall be available at no cost from the Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, 611 W. Ottawa St., Lansing, MI 48909 or on the department's website at www.michigan.gov/healthlicense.

History: 2014 AACS.

R 338.3623 Eligible participants; requirements.

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.

History: 2014 AACS.

R 338.3625 Dispensing donated prescription drugs; requirements.

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

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(3) The department and a local participating pharmacy or charitable clinic shall remove any patient identifying information from the package prior to dispensing the drugs.

(4) Prescription drugs donated under this program shall not be resold; however, a participating pharmacy or charitable clinic may collect a handling fee pursuant to 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 drug a handling fee, not to exceed 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 handling fee does not exceed the total cost of obtaining the 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 prescription drug dispensed through the program shall not be eligible for reimbursement under the medical assistance program.

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

History: 2014 AACS.

R 338.3629 Donation to other participating pharmacy or charitable clinic.

Rule 29. The originating participating pharmacy or charitable clinic may donate drugs donated under this program to other participating pharmacies or charitable clinics for use pursuant to the program. The participating pharmacy or charitable clinic donating the drugs shall complete a transfer form.

History: 2014 AACS.

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

History: 2014 AACS.

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

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

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

(4) The collection shall occur on-site at the participating pharmacy or charitable clinic and according to these rules and all applicable state and federal laws and regulations.

History: 2014 AACS.

R 338.3635 Collection device; requirements.

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

(a) Is designed to allow contents to be added to the device but not removed, except by authorized personnel for the purpose of destruction and disposal.

(b) Is labeled pursuant to all applicable state and federal laws and regulations.

(c) Is lined with a removable liner that is waterproof, tamper-evident, tear resistant, and capable of being sealed. The contents of the liner shall not be viewable from the outside and the size or capacity of the liner shall be clearly marked on the outside of the liner.

(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 satisfy the requirements of this rule, provided the participating pharmacy or charitable clinic is a compliant participant in the yellow jugs old drugs program.

History: 2014 AACS.

R 338.3637 Access; destruction of collected drugs.

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

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

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

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

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

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

(b) Upon being accessed, the liner shall be immediately sealed and the weight of the contents immediately recorded in the destruction and disposal log. A copy of the destruction log shall 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) Within 1 year of collection, the contents of the collection device shall be transferred to a waste disposal facility for destruction.

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

History: 2014 AACS.

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 participating pharmacy or charitable clinic shall maintain a destruction and disposal log that includes all of the following information:

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

(b) Date, time, 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 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 be stored with the destruction log, as applicable.

History: 2014 AACS.

R 338.3641 Transportation.

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

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History: 2014 AACS.

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

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

History: 2014 AACS.

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