DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
PHARMACY – PROGRAM FOR UTILIZATION OF UNUSED PRESCRIPTION DRUGS
EMERGENCY RULES

CERTIFICATE OF NEED FOR EXTENSION OF EMERGENCY RULES

Pursuant to Section 48(1) of 1969 PA 306, as amended, MCL 24.248(1), I hereby certify that it is necessary to extend the effectiveness of the Pharmacy – Program For Utilization Of Unused Prescription Drugs Rules, which were filed with the Secretary of State on October 16, 2013, for an additional 6 months. Therefore, the Pharmacy – Program For Utilization Of Unused Prescription Drugs Emergency Rules shall remain effective until October 16, 2014, or until such time as identical or similar rules are promulgated pursuant to Section 48(2) of 1969 PA 306, as amended, MCL 24.248(2).

Rick Snyder, Governor

3/21/14
Date
These rules take effect upon filing with the Secretary of State and shall remain in effect for 6 months.

(By authority conferred on the Department of Licensing and Regulatory Affairs by Section 17775 of 1978 PA 368, MCL 333.17775, and Executive Reorganization Order No. 2011-4, MCL 445.2030)

FINDING OF EMERGENCY

These rules are promulgated by the Department of Licensing and Regulatory Affairs to administer the unused prescription drug repository and distribution program, 2012 PA 383, MCL 333.17775, effective March 28, 2013. Under the program, unused or donated prescription drugs, other than controlled substances, from an eligible health facility or manufacturer may be transferred to a pharmacy or charitable clinic to be dispensed to eligible participants who lack health insurance or reasonable means to pay for prescriptions. Pharmacies and charitable clinics that participate in the program may also collect unwanted prescription drugs for destruction and disposal.

The act, specifically section 17775(12), requires the department, in consultation with the Board of Pharmacy, to promulgate emergency rules under the administrative procedures act on or before the expiration of 6 months after the effective date of the act to establish, implement, and administer the program.

Therefore, the Department of Licensing and Regulatory Affairs finds the statutory requirement included in section 17775(12) of the act requires promulgation of these emergency rules without following the notice and participation procedures required by sections 41 and 42 of 1969 PA 306, MCL 24.241 and 24.242.

Rule 1. Definitions.

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.

(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) “Code” means 1978 PA 368, MCL 333.1101 to 333.25211.

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

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

(e) "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.

   (f) "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.

      (ii) A physician's assistant licensed under part 170, 175, or 180 of the code.

      (iii) A dentist licensed under part 166 of the code.

      (iv) An optometrist licensed under part 174 of the code.

      (v) A pharmacist licensed under part 177 of the code.

      (vi) A podiatrist licensed under part 180 of the code.

   (g) “Non-retrievable” means to permanently alter a drug’s physical state, chemical state, or both, through irreversible means in order to render that drug unavailable and unusable for all practical purposes.

   (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.

   (i) “Reverse distributor” means an entity that collects controlled or noncontrolled substances from a health facility or pharmacy and either returns them to the manufacturer or arranges for their disposal.

   (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.

Rule 2. Eligibility criteria; pharmacy; charitable clinics; requirements; withdrawal.

(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, 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 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 subdivision (a) of rule 1.

(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 Michigan license or registration number of pharmacy or charitable clinic.

(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.

Rule 3. Eligible prescription drugs.

(1) All non-controlled prescription drugs, except those specified in rule 4, 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.

Rule 4. Ineligible drugs; controlled substances prohibited.

(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.

Rule 5. Donated prescription drugs; participating pharmacy or charitable clinic requirements.  
(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 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.

Rule 6. Donated prescription drugs; eligible facility requirements.  
(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 professional samples, other than controlled substances, to a charitable clinic under the program, if the drug meets the requirements of these rules.

Rule 7. Resident of an eligible facility; donations permitted.  
(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, 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.

Rule 8. Transfer and shipment of donated drugs; requirements.

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.

Rule 9. Inspection and storage of donated prescription drugs; destruction; recall.

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 destruction and disposal record shall be created and maintained 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.

Rule 10. Record keeping; inventory; requirements.

(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) All of the following information shall be documented 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.

(3) 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.

Rule 11. Forms; eligible facility donation form, resident donation form, eligible participant form, transfer form, destruction form; requirements.

(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, 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, 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, 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 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, 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, Michigan license or registration number, and the name, 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 the state of Michigan.

(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, Michigan license or registration number, address, telephone number, and the name, dated signature, and Michigan license number of 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#), 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 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, Michigan license number, address, and telephone number, and 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.

Rule 12. Eligible participants; requirements.
   The eligible participant shall complete the recipient form attesting to the following statements:
   (a) 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.
   (b) The eligible participant acknowledges that the drugs have been donated.
   (c) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the poison prevention packaging act, 15 U.S.C. §1471–1477.

Rule 13. Dispensing donated prescription drugs; requirements.
   (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.
   (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 Rule 14.

(1) A participating pharmacy or charitable clinic may charge the eligible participant of 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.

(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.

Rule 15. Donation to other participating pharmacy or charitable clinic.

(1) 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.

Rule 16. Registry; creation.

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.

Rule 17. Collection of prescription drugs and other medication for destruction and disposal; requirements; limitations.

(1) Pursuant to section 17776 of the code, 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) Controlled substances shall not be collected by a participating pharmacy or charitable clinic for destruction and disposal, unless permitted by federal law.

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

Rule 18. Collection device; requirements.

(1) 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) The collection device 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) The collection device shall be 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.

(c) The collection device 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.

(d) The collection device utilizes a design that is tamper resistant and is securely locked.

(e) The collection device shall be securely fastened to permanent structure within the designated pharmacy area so that it cannot be removed.

(f) The collection device shall be consistently monitored by security features and pharmacy personnel.

(g) The following statement 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.”

Rule 19. Destruction of collected drugs; methods; access.

1) Destruction of collected drugs shall occur through 1 of the following methods:

   a) On-site at the participating pharmacy or charitable clinic. The method of the on-site destruction shall be sufficient to render the prescription drugs non-retrievable to prevent diversion and to protect the public health and safety. On-site destruction shall occur immediately after the contents are removed from the collection device.

   b) Off-site, through a contract with a reverse distributor. The participating pharmacy or charitable clinic may contract with a reverse distributor to facilitate the destruction and disposal of drugs collected under the program. Off-site destruction shall occur not more than 7 days after the contents have been removed from the collection device.

   2) Only personnel designated by the participating pharmacy or charitable clinic shall have access to the collection device to remove the contents for on-site destruction or to transfer the contents to the party performing the destruction and disposal services.

   3) The collection device shall be accessed only to remove the contents for destruction in a manner consistent with these rules.

   4) Two authorized personnel, 1 of whom shall be a licensed pharmacist, shall access the collection device to remove the contents for destruction. The liner containing the contents shall be sealed immediately upon removal and the weight shall be recorded on the destruction and disposal log. The destruction and disposal log shall be completed at the time the collection receptacle is accessed.

   5) If the contents of the collection receptacle are going to be transferred to a reverse distributor for destruction, a copy of the destruction log shall be included with the sealed contents.

Rule 20. Record keeping; policy and procedures; destruction and disposal log.

1) In addition to the policy and procedure requirements in Rule 9 and Rule 10, 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 Michigan license or registration number of the participating pharmacy or charitable clinic.

(b) Date, time, weight of the contents of the collection receptacle and method of destruction utilized each time the contents of the collection receptacle are removed for destruction.

(2) Copies of all contracts with reverse distributors shall be stored with the destruction log, as applicable.


(1) If it is necessary to transport the contents of the collection device to the location of the reverse distributor for the destruction and disposal, the transportation shall be done through a common carrier and in manner that allows the shipment to be tracked and delivery confirmed.

(2) Utilization of a vehicle or mode of transportation that is primarily used by the participating pharmacy or charitable clinic for business or personal purposes is prohibited.

Rule 22. Department of human services and department of community health; inclusion in rule-making process.

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.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

________________________________________
Steve Arwood, Director

CONCURRENCE OF THE GOVERNOR

Pursuant to Section 48(1) of 1969 PA 306, MCL 24.248(1), I hereby concur in the finding of the Department of Licensing and Regulatory Affairs that circumstances creating an emergency have occurred and the public interest requires the promulgation of the following rule(s).

________________________________________    __________________
Rick Snyder, Governor      Date