

**Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 2—General Rules**

**PROPOSED RULE**

**20 CSR 2220-2.095- Collection of Non-Controlled Medication for Destruction**

***PURPOSE:** The purpose of this rule is to authorize pharmacies to collect medication for purposes of destruction and to establish requirements for medication collection programs.*

- (1) The provisions of this rule shall apply to the collection of non-controlled medication from the public for destruction. Participation in a medication return or destruction program is voluntary. This rule shall not be construed to require that a licensee or permit holder participate in or establish a return/destruction program. Pharmacies collecting controlled substances must comply with all applicable state and federal controlled substance laws.
- (2) Definitions. The following definitions shall apply for purposes of this rule:
  - (A) “Mail”- Mail shall include mailing via the United States postal service or shipping via a common carrier.
  - (B) “Nonretrievable”- For the purposes of destruction, a condition or state to which medication is rendered after undergoing a process that permanently alters the medication’s physical condition or state through irreversible means and thereby renders the medication unavailable and unusable for all practical purposes.
- (3) Pharmacies may maintain a collection receptacle or establish an authorized mail-back program to collect non-controlled medication from the general public for destruction. Collection receptacles may not be used to dispose of unused/unwanted medication in the pharmacy’s inventory (e.g., outdated drugs, medical waste). Collected medication shall not be resold or reused.
  - (A) Pharmacies collecting medication under this rule shall develop and implement written policies and procedures governing medication collection which must include, but not be limited to, authorized destruction procedures and methods.
  - (B) This rule does not preempt or modify return/reuse of medication as authorized by 20 CSR 2220-3.040, the provisions of Chapter 196, RSMo, governing the Prescription Drug Repository Program, or any provision of state or federal law governing controlled substances or the destruction, handling, or transporting of medical or pharmaceutical waste.
- (4) Collection Receptacles. Pharmacies that maintain a collection receptacle to collect non-controlled medication for destruction must comply with the following:
  - (A) Collection receptacles must be securely placed and maintained inside the physical building of the pharmacy in a manner that prevents theft, diversion, or unauthorized

removal. Receptacles must be securely fastened to a permanent structure. The receptacle must be visible to pharmacy staff at all times and shall not be located in or near exit doors.

- (B) The receptacle must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the pharmacy is closed for business.
  - (C) A sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. If the receptacle is also used to collect controlled substances, the required sign must comply with state and federal controlled substance laws.
  - (D) Inner liners must be removable, waterproof, tamper-evident, and tear resistant and must bear a permanent, unique identification number or identifier that enables the inner liner to be tracked. The contents of the inner liner shall not be viewable from the outside.
  - (E) Inner liners must be installed or removed from a collection receptacle by or under the supervision of at least two (2) board licensees or registrants. Inner liners must be immediately sealed once removed from the receptacle; the sealed inner liner shall not be opened, x-rayed, analyzed or otherwise penetrated by the pharmacy or pharmacy staff. After removal, sealed inner liners pending destruction may be stored at the pharmacy in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than thirty (30) business days.
  - (F) Pharmacies must report any theft or diversion of or from a collection receptacle to the board in writing within fourteen (14) days in a manner designated by the board.
- (5) Mail-Back Programs. Pharmacies may provide mail-back packages to the public for the purpose of mailing medication to a collector that is authorized by the Drug Enforcement Administration or federal law to receive prescription medication for destruction (“an authorized collector”). Packages may be provided directly by the pharmacy or the pharmacy’s authorized designee, provided the pharmacy is responsible for ensuring compliance with this section.
- (A) Mail-back packages must be preaddressed with the address of the authorized collector. The cost of shipping the package shall be postage or otherwise prepaid. Licensees/permit holders shall not accept any returned mail-back packages. Packages must be mailed directly to the authorized collector by the consumer or his/her agent.
  - (B) Mail-back packages must be nondescript and shall not include any markings or other information that might indicate that the package contains medication. Packages must be water-proof, spill-proof, tamper-evident, tear-resistant, and sealable.
  - (C) Mail-back packages must be provided with instructions for mailing, notice that packages may only be mailed from within the fifty (50) United States or U.S. territories and notice that only packages provided by or on behalf of the pharmacy may be used to mail medication.

- (D) Senders shall not be required to provide any personally identifiable information when mailing back medication.
  - (E) Mail-back packages must include a unique identification number or other unique identifier that enables the package to be tracked.
- (6) Long-Term Care Facilities: Pharmacies may provide and maintain a collection receptacle at a long-term care facility to collect medication from the public or facility residents for destruction. This section does not apply to medication collected for return and reuse as authorized by 20 CSR 2220-3.040.
- (A) Collection receptacles must be securely placed and maintained inside the physical building of the long-term care facility in a manner that prevents theft, diversion, or unauthorized removal. Receptacles must be securely fastened to a permanent structure and must be visible to the facility's staff at all times. In lieu of fastening to a permanent structure, receptacles that are not accessible to the public or residents may be stored in a securely locked room or area with controlled access that is restricted to facility staff/personnel until transfer to the pharmacy. Collection receptacles shall not be located in or near exit doors.
  - (B) Collection receptacles must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with section (4)(D) and (E) of this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the facility is closed for business.
  - (C) If the receptacle is accessible to the public or residents, a sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. The required sign must comply with state and federal controlled substance laws if the receptacle is also used to collect controlled substances,
  - (D) The pharmacy shall be responsible for installing, managing, and maintaining the receptacle and for the removal, sealing, transfer, and storage of inner liners and receptacle contents.
  - (E) Inner liners may only be installed, removed, and transferred either: (1) by or under the supervision of two (2) board licensees or registrants acting on behalf of the pharmacy or (2) by or under the supervision of a board licensee/registrant and an employee/staff member of the long-term care facility designated by the pharmacy (e.g., a supervisory charge nurse).
  - (F) After removal, sealed inner liners may be stored at the facility in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than three (3) business days.
- (7) Destruction Methods. Medication collected for destruction shall be rendered nonretrievable and destroyed in compliance with all applicable federal and state laws. Medication shall be destroyed in one of the following ways:

- (A) On-site Destruction: Medication may be destroyed on the physical premises of the pharmacy, provided two (2) board licensees or registrants must personally witness the destruction of the medication and handle or observe the handling of the medication until the substance is rendered non-retrievable.
  - (B) Transfer to an Authorized Entity: Collected medication may be mailed, shipped, or transferred to an entity authorized to destroy the medication offsite, provided two (2) board licensees or registrants must witness or observe the mailing, shipping, or transfer. If medication is transported by the pharmacy to the offsite location, the medication must be constantly moving towards its final location. Unnecessary and unrelated stops and stops of an extended duration shall not occur.
- (8) Records. Except as otherwise provided herein, pharmacies shall maintain a complete and accurate record of the following for two (2) years:
- (A) Inventories. Pharmacies shall conduct an inventory every twelve (12) months of inner-liners that are present at the pharmacy or at a long-term care facility that are unused or awaiting destruction. The inventory shall be documented in writing and must include:
    - 1. The date of the inventory;
    - 2. The number of inner liners present on the date of the inventory and the size of any inner liners (e.g., five 10-gallon liners, etc.);
    - 3. The unique identification number/identifier of each inner liner, whether unused or awaiting destruction.
  - (B) Inner Liners. The pharmacy must maintain the following written records for inner liners:
    - 1. The unique identification number/identifier and the size of each unused inner liner (e.g., 5-gallon, 10-gallon, etc.);
    - 2. The date each inner liner is installed, the address of the location where each liner is installed, the unique identification number/identifier and size of each installed inner liner, and the names and signatures of the two (2) required witnesses for each installation; and
    - 3. The date each inner liner is removed and sealed, the unique identification number/identifier of each removed inner liner, and the names and signatures of the two (2) required witnesses for each removal.
  - (C) Destruction. The pharmacy must maintain the following written records:
    - 1. For medication destroyed on-site of the pharmacy, the date and method of destruction, the unique identification number/identifier of each inner liner destroyed and the names and signatures of the two (2) required witnesses of the destruction.
    - 2. For medication destroyed off-site, the date each inner liner was transferred for destruction, the name and address of each entity to whom each sealed inner liner was transferred for destruction, the unique identification number/identifier of each inner liner transferred for destruction and the name of the two (2) required witnesses for medication transfer or transport.
- (9) Law Enforcement Return Programs. Licensees/permitholders shall be exempt from compliance with this rule when participating in medication collection programs conducted by local, state, or federal law enforcement agencies provided:

- (A) Collected medication is placed into a collection container or area that is under the supervision of law enforcement personnel at all times;
- (B) Law enforcement personnel are present whenever drugs are collected or on site; and
- (C) The licensee/permitholder does not take possession of the collected medications. Collected medications must remain under the control of, and must be removed by, law enforcement.

*AUTHORITY: sections 338.140, 338.240, RSMo Supp. 2013, section 338.280, RSMo 2000, and section 338.315, RSMo Supp. 2014. Original rule filed August 30, 2016.*

*PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.*

*PRIVATE COST: This proposed rule will cost private entities voluntary electing to establish a medication return program an estimated three hundred and six thousand and four hundred dollars (\$306,400) during the first year of implementation and thirty-five thousand, four hundred and seventy three dollars and forty-six cents (\$ 35,473.46) annually over the life of the rule as the result of the proposed amendment.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at [pharmacy@pr.mo.gov](mailto:pharmacy@pr.mo.gov). To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.*