

**Title 19—DEPARTMENT OF HEALTH AND  
SENIOR SERVICES  
Division 30—Division of Regulation and Licensure  
Chapter 1—Controlled Substances**

**PROPOSED AMENDMENT**

**19 CSR 30-1.078 Disposing of Unwanted Controlled Substances.** The division is amending section (1) and repealing sections (2)-(4), to be replaced with new sections (2) and (3).

*PURPOSE: This rule amendment establishes processes for authorized registrants to collect unwanted controlled substances through collection receptacles or a mail-back program, as allowed by 21 CFR Part 1300 to end.*

(1) A registrant in possession of any controlled substance(s) and desiring or required to dispose of such substance(s) shall:

- (A) Return the controlled substances to the original supplier;
  - (B) Transfer the controlled substances to a distributor authorized to accept controlled substances for the purpose of disposal;
  - (C) Submit a DEA Form 41 to the federal Drug Enforcement Administration requesting authorization to dispose of the controlled substances in compliance with federal regulations;
  - (D) Authorized Collectors of Controlled Substances. Registrants shall dispose of all unwanted controlled substances in a manner as authorized in 21 CFR Part 1317 and record keeping in 21 CFR Part 1304. Only manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals, and retail pharmacies that have modified their state and federal controlled substances registrations may possess a collection receptacle for medication disposal or participate in the DEA approved mail-back system;**
- [(D)]* (E) Contact the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Health and Senior Services for information pertaining to subsections (1)(A), (B), *[or]* (C) or **(D) of this rule.**

*[(2) The return, transfer or disposal of any controlled substance shall be documented in accordance with 19 CSR 30-1.044.]*

**(2) Destruction of controlled substances contaminated by patient contact in patient care areas.**

- (A) Controlled substances that have been contaminated by patient contact are to be destroyed on site. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to administration shall also be destroyed on site.**
- (B) Controlled substances that have not been contaminated by patient contact or are not excess volumes of a dosage unit shall not be destroyed on site unless the**

registrant has obtained authorization from the United States Drug Enforcement Administration to destroy such drugs and destruction is documented on the DEA Form 41. Unwanted controlled substances that have been expired, discontinued, or are otherwise unwanted shall be disposed of by methods listed previously in subsections (1)(A), (B), (C) or (D) of this rule.

(C) In a hospital patient care area, unwanted controlled substances that have not been contaminated by patient contact shall be returned to the pharmacy for final disposal.

(D) The destruction of controlled substances shall be in such a manner that it renders the medication unrecoverable and beyond reclamation so that it cannot be diverted.

(E) The destruction and documentation of destruction shall be performed by two (2) people. One of the people must be a licensed physician, nurse, pharmacist, intern pharmacist, or pharmacy technician, assistant physician, physician assistant, podiatrist, optometrist, dentist or veterinarian. The second person who is a witness is not required to be a licensed medical professional but must be an employee of the registrant, or a licensed practitioner of the hospital if in an EMS setting.

(F) The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number if applicable, and the names or initials of the two employees performing the destruction. The controlled substance administration or destruction records are to be retained for two years and available for inspection by the Department of Health and Senior Services' investigators;

*[(3) In the event the registrant is a hospital, the following procedures are to be used for the destruction of controlled substances:*

*(A) When disposal of controlled substances is in patient care areas—*

*1. Controlled substances which are contaminated by patient body fluids are to be destroyed by a physician, nurse or a pharmacist in the presence of another hospital*

*employee;*

*2. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use shall be destroyed by a nurse, pharmacist or physician*

*in the presence of another hospital employee;*

*3. The remaining contents of opened glass ampules of controlled substances shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;*

*4. Single units of single dose packages of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee or returned to the pharmacy for destruction;*

5. *The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substance administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;*

6. *All other controlled substances which are not patient contaminated but which are to be disposed of shall be returned to the pharmacy for disposal;*

*(B) When disposal of controlled substances is in the pharmacy—*

*1. Single units of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a pharmacist in the presence of another hospital employee or held for later destruction;*

*2. All other controlled substances which are not patient contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.]*

**(3) Collection Receptacle Boxes for Patients' Unwanted Prescriptions.**

**(A) Hospitals, pharmacies, narcotic treatment programs and long-term care facilities are authorized to install collection receptacle boxes or participate in a DEA approved mail-back method to collect unwanted controlled substance prescription medications from patients. Registrants must comply with all the security and record keeping provisions in 21 CFR part 1317. Collection receptacles are for patients' unwanted medications only and not for the expired or unwanted stock of a practitioner or facility.**

**(B) All facilities and locations with collection receptacle boxes and mail-back systems shall comply with Code of Federal Regulations, Title 21 Part 1317.**

**1. Patients' medications from long-term care facilities and narcotic treatment programs shall be placed in a receptacle within three (3) days of the expiration date on the medication; or upon a discontinuation of use authorized by a prescriber; or upon the death of a patient.**

**2. A retail pharmacy or hospital pharmacy must install, maintain, and manage the collection receptacle box.**

**(C) Record keeping for collection receptacle boxes. Pursuant to federal regulations, the registrants or their employees are not to inventory the contents of the collection receptacle box. The collection receptacle box is to be opened by two (2) people; one being an employee of the pharmacy and the second person may be an employee of the facility receiving pharmaceutical services. All registrants with collection receptacle boxes shall maintain a perpetual log that documents entry into the collection receptacle box, changing of liners, and transfers of drugs from the registrant to a reverse distributor. These logs shall be maintained on file at the registered location for inspection and document the date of entries into the**

**collection receptacle box, the names of the employees entering the collection receptacle box, the reason for entering the receptacle, the serial number of a liner being removed, and the serial number of a new liner being installed. This log shall also be used to document the transfer of a liner from the registrant to a reverse distributor by documenting the date of transfer, serial number of the liner, names of the persons involved in the transfer, and the DEA number of the reverse distributor. For drugs placed in the collection receptacle box, the facility shall maintain a log that documents the date, time, patient name, drug name, drug strength, form, quantity of drugs disposed of, the reason for the disposal, and the name of the two (2) people performing the disposal and placement in the collection receptacle box. The log shall also document when the pharmacy changes out the interior liner bags and documents the serial number of the bag being removed and of the new bag being installed.**

*[(4) If the registrant administers controlled substances and is not a hospital, the following procedures are to be used for the destruction of controlled substances:*

*(A) Controlled substances which are contaminated by patient body fluids are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;*

*(B) An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use is to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;*

*(C) The remaining contents of opened glass ampules of controlled substances which are not patient contaminated are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;*

*(D) When the controlled substance is destroyed by the registrant or designee authorized to administer, the following shall be entered in the controlled substances administration records or a separate controlled substances destruction record: the date and amount destroyed, the reason for destruction and the registrant's name and address. The registrant or designee doing the destruction and the witnessing employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substances administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;*

*(E) All other controlled substances which are not patient-contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.]*

*AUTHORITY: sections 195.050 and 195.195, RSMo [1994]2017.\* Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed MONTH, DATE, YEAR, effective MONTH, DATE, YEAR, expires MONTH, DATE, YEAR. A proposed rule covering this same material is published in this issue of the Missouri Register.*

*\*Original authority: 195.050, RSMo 1939, amended 1971, 1989, 2017 and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2017.*

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

*PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.*

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed amendment, by contacting Michael Boeger with the Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*