

# Emergency Rules

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

**EMERGENCY AMENDMENT**

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

*PURPOSE: This amendment establishes the process for authorized registrants to collect unwanted controlled substances through collection receptacles or a mail-back program and amends requirements for destruction of controlled substances by registrants.*

*EMERGENCY STATEMENT: Opioid abuse is a public health crisis in Missouri and throughout the country. In 2016, there was a thirty-five percent (35%) increase in opioid overdose deaths over 2015. During 2016, one (1) out of every sixty-six (66) deaths was opiate related. Additionally, the number of infants born with opiate-related natal abstinence syndrome is increasing. Studies have found that a large percentage of people who abuse controlled substances get those substances from family members, homes, and leftover prescriptions. One (1) way to impact the opioid crisis is to provide methods for safe, efficient disposal of extra or unwanted controlled substances, including opioids, so that they are not diverted. Prior to portions of Senate Bill 826 (2018) taking effect, Missouri's controlled substance law prohibited collection of controlled substances by registrants who had not originally prescribed the substance. This meant that pharmacies and other registrants could not maintain collection receptacles for disposal of unwanted controlled substances by customers and patients. Drug take-back events were allowed, and four (4) such events collected tens of thousands of pounds of drugs during 2016 and 2017. Now that Senate Bill 826 (2018) is in effect, amendments to this regulation are necessary to implement the provisions of the bill so that registrants can begin maintaining collection receptacles as soon as possible. Without such receptacles, people who wish to properly dispose of controlled substances must retain them in their homes until a take-back event is held, increasing the risk that the substances will be diverted before they can be disposed. This emergency amendment is necessary for the immediate protection of the public health, safety, and welfare due to the current opioid crisis. The department finds a compelling governmental interest in protecting public health and safety from the opioid crisis, which requires this emergency action. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The department believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed September 17, 2018, becomes effective September 27, 2018, and expires March 25, 2019.*

(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 substance(s) to the original supplier;

(B) Transfer the controlled substance(s) to a distributor authorized to accept controlled substance(s) for the purpose of disposal;

(C) Submit a DEA Form 41 to the federal Drug Enforcement Administration (DEA) requesting authorization to dispose of the controlled substance(s) in compliance with federal regulations;

(D) **Become an Authorized Collector of Controlled Substance(s). Registrants shall dispose of all unwanted controlled substance(s) and keep records in accordance with federal regulations. 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 substance(s) in patient care areas.

(A) Controlled substance(s) 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 substance(s) 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 section (1) of this rule.

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

(D) The destruction of controlled substance(s) 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 and completed by two (2) people. One (1) of the people must be a licensed physician, nurse, pharmacist, intern pharmacist, pharmacy technician, assistant physician, physician assistant, podiatrist, optometrist, dentist, or veterinarian. The second person, the witness, is not required to be a licensed medical professional but must be an employee of the registrant, unless in an Emergency Medical Service (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, the patient's name and room number if applicable, and the names or initials of the two (2) persons performing the destruction. The controlled substance administration and destruction records are to be retained for two (2) years and available for inspection by the Department of Health and Senior Services;

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

(A) When disposal of controlled substance(s) 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 substance(s) 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 substance(s) which are contaminated other than by patient body fluids and are not an infectious hazard, [or] have been removed from their original or

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# Emergency Rules

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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(s) 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 (2) 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 substance(s) is in the pharmacy—

1. Single units of controlled substance(s) 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.

*[(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.]*

#### **(4) Collection Receptacle Boxes for Patients' Unwanted Controlled Substance 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 federal regulations regarding security and record keeping. Collection receptacles shall be used only for patients' unwanted medications 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 federal regulations.**

**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; upon a discontinuation of use authorized by a prescriber; or upon the death of a patient.**

**2. Collection receptacle boxes shall be installed, maintained, and managed by a retail pharmacy or hospital pharmacy.**

**(C) Record keeping for collection receptacle boxes. Registrants or their employees shall not inventory the contents of the collection receptacle box. The collection receptacle box is to be opened by two (2) people; one (1) shall be an employee of the pharmacy and the other 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 shall 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. The log shall also document when the pharmacy changes out the interior liner bags and document the serial number of the bag being removed and of the new bag being installed.**

*AUTHORITY: sections 195.050 and 195.195, RSMo [1994] Supp. 2018. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expires March 25, 2019. An emergency amendment and a proposed amendment covering this same material will be published in the October 15, 2018, issue of the Missouri Register.*