



Rx Cares for Missouri
Medication Destruction and Disposal Program
Participant Application

IMPORTANT INFORMATION:

1. This application is for potential participants in the Rx Cares for Missouri Medication and Destruction Program (the "Program"). A Rx Cares for Missouri Informational Guide is included in this application packet along with Board rule 20 CSR 2220-2.990 governing Program operations. Interested parties should review the Informational Guide and 20 CSR 2220-2.990 for important Program compliance and eligibility requirements before submitting an application. The Board also recommends reviewing DEA and BNDD rules governing authorized controlled substance collectors (*see the Board's website*).
2. To be eligible for participation, applicants must be one of the following:
 - A licensed Missouri pharmacy or drug distributor
 - A hospital/clinic with an onsite pharmacy
 - A narcotic treatment program, or
 - A federal, state, tribal or local law enforcement agency (collection receptacles must be located inside the law enforcement agency's physical address)

Proof of eligibility must be submitted with your application. You ARE NOT eligible to apply unless you are one of the entities listed above.

3. Non-law enforcement applicants must be currently registered with the United States Drug Enforcement Administration ("DEA") and the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") as an authorized collector of controlled substances for purposes of disposal (*registration is not required for law enforcement agencies*). Proof of your DEA and BNDD authorized collector registration must be submitted with your application (e.g., a copy of the registrations, other official verification). Applications without proof of DEA/BNDD registration as an authorized collector will be returned and not processed.

Note: An authorized collector registration is different from, and in addition to, a DEA/BNDD registration to dispense, prescribe or otherwise store controlled substances. Your current DEA/BNDD registration will need to be modified to add authorization to collect controlled substances for disposal, if not already completed.

4. Applicants must designate a site that is physically located in Missouri where the collection receptacle will be located. The Bd. will not approve applications for collection receptacles that will not be located in this state.
5. If approved, collections receptacles must be open to the public and may not be used to dispose of medication from the applicant's drug inventory. Violations of this requirement may result in disciplinary action or termination from the Program.
6. Controlled substances must be collected and disposed of in accordance with applicable state and federal controlled substance laws.
7. At the discretion of the Board, applicants will be approved for Program participation subject to funding availability. See rule 20 CSR 2220-2.990 for approval criteria (See attached)
8. The board has contracted with Sharps Compliance, Inc., to operate the Program as part of their Medsafe® initiative. Pursuant to rule 20 CSR 2220-2.990, approved Participants must enroll in the

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Medsafe® program and comply with Medsafe® program requirements. This includes completing the included Medsafe® policy agreement. An instructional video on the Medsafe® program is available on the Board's website.

9. Please allow 3-4 weeks for Bd. review and approval. Notification of approval will be provided to the Participant's designated representative listed on the application. After approval, Medsafe® enrollment information will be provided by the Board/Sharps Compliance.

APPLICATION CHECKLIST:

- Completed and Signed Application Form: Incomplete applications will be returned for correction.
- Signed Copy of the Medsafe® Policy Agreement (*Required for Program participation*)
- Copies of DEA & BNDD Collector Registrations for Non-Law Enforcement Agencies: Applicants must be currently registered with the DEA and BNDD as an authorized collector of controlled substances for purposes of disposal (*law enforcement agencies are not required to be registered*). Application and registration information is available online at:

United States Drug Enforcement Administration
Kansas City District Office
7600 College Blvd.
Overland Park, KS
(888) 803-1179
(314) 538-4628
https://www.deadiversion.usdoj.gov/online_forms_apps.html

United States Drug Enforcement Administration
St. Louis Division Office
317 South 16th Street
St. Louis, Missouri
(888) 803-1179
(314) 538-4628
https://www.deadiversion.usdoj.gov/online_forms_apps.html

Missouri Bureau of Narcotics and Dangerous Drugs (BNDD)
P.O. Box 570
Jefferson City, MO 65102
(573) 751-6321
bndd@health.mo.gov



RX CARES FOR MISSOURI MEDICATION DESTRUCTION AND DISPOSAL PROGRAM PARTICIPANT APPLICATION

<p>SUBMIT THIS COMPLETED APPLICATION TO:</p> <p><u>MAILING ADDRESS</u> MISSOURI BOARD OF PHARMACY P.O. Box 625 JEFFERSON CITY, MO 65102</p> <p><u>OVERNIGHT ADDRESS</u> MISSOURI BOARD OF PHARMACY 3605 MISSOURI BOULEVARD JEFFERSON CITY, MO 65109</p> <p>✓ SEE INSTRUCTION SHEET FOR COMPLETION OF THIS FORM ✓ KEEP A COPY OF COMPLETED APPLICATION FOR YOUR RECORDS</p>	FOR OFFICE USE ONLY
	LICENSE #
	ACTION DATE
	NOTES

SECTION A: APPLICANT INFORMATION				
APPLICANT'S NAME			MO PHARMACY/DRUG DISTRIBUTOR LIC. # <i>(if applicable)</i>	
APPLICANT ADDRESS (STREET)		(CITY)	(STATE)	(ZIP)
APPLICANT TELEPHONE #		FACILITY E-MAIL ADDRESS		
<i>DESIGNATED REPRESENTATIVE: Identify a designated contact person for questions regarding this application or Program operations.</i>				
DESIGNATED REPRESENTATIVE NAME			POSITION/TITLE	
CONTACT MAILING ADDRESS (STREET)		(CITY)	(STATE)	(ZIP)
CONTACT TELEPHONE #			CONTACT FAX #	
CONTACT E-MAIL ADDRESS				
<i>ELIGIBILITY: To participate in the Rx Cares for Missouri Program, the applicant must be one of the entities listed below. <u>Proof of eligibility must be submitted with this application.</u></i>				
The above applicant is (Check all that apply):				
<input type="checkbox"/> A licensed Missouri pharmacy or drug distributor <input type="checkbox"/> A hospital/clinic with an onsite pharmacy <input type="checkbox"/> A narcotic treatment program, or <input type="checkbox"/> A federal, state, tribal or local law enforcement agency <p style="text-align: center;"><i>***Proof of eligibility must be submitted with this application***</i></p>				
<i>Controlled Substance Registration:</i>				
For non-law enforcement agencies: Is the applicant registered with the United States Drug Enforcement Administration and the Missouri Bureau of Narcotics and Dangerous Drugs as an authorized collector of controlled substances for purposes of disposal? <input type="checkbox"/> YES <input type="checkbox"/> NO <p style="text-align: center;"><i>**Law enforcement applicants do not have to be registered [see 21 CFR § 1317.35]. All other applicants must be <u>currently</u> registered with the DEA/BNDD as an authorized collector. Proof of DEA/BNDD collector registration must be submitted with this application.**</i></p>				

Collection Receptacles: Provide the physical address where the collection receptacle will be located (the receptacle must be physically located at the authorized collector's DEA/BNDD registered address or the physical address of a law enforcement agency)

(STREET) (CITY) (STATE) (ZIP)

SECTION B: PROGRAM OPERATIONS

Pursuant to 20 CSR 2220-9.990, provide the following information regarding the proposed collection program. This information will be used by the Board in assessing your application. Attach additional sheets if necessary.

1. Why is a medication collection program needed in the proposed collection site area? Provide any relevant evidence or data regarding drug use, abuse, fatalities or trends supporting the need for the proposed collection site.

2. Describe the nature and structure of the proposed collection program, including, but not limited to, operational times and any public restrictions.

3. List available staff, resources or expertise to support the collection program (*provide resumes or employment history, if applicable*)

4. Answer the following questions:

- a. Has the applicant previously been approved by the Board for other collection sites as part of the Rx Cares for Missouri Program?
 - YES (*provide a list of approved collection sites*)
 - NO

- b. Has the applicant ever had any state, federal or local disciplinary action taken against any pharmacy, drug, controlled substance or healthcare related license, registration, permit, certificate or authorization held by the applicant?
 - YES (*provide an explanation and any disciplinary orders/documents*)
 - NO

- c. Has the applicant or any owner, partner, officer of the applicant ever had any controlled substance registration, license, permit, or certificate denied, disciplined or refused in this state, or any other state or country?
 - YES (provide copies of any denial/refusal/disciplinary documents)
 - NO

- d. Has the applicant ever been excluded from participation in any state or federally funded health care program such as Medicare, Medicaid or MO HealthNet for fraud, abuse, or submission of any false or fraudulent claim, payment or reimbursement request?
 - YES (provide an explanation and related documents)
 - NO

5. Identify any other factor that may be relevant to the Board's consideration of the applicant's ability to participate in or comply with the Rx Cares for Missouri Program? (Attach additional sheets if needed)

SECTION C: APPLICANT AFFIDAVIT

This affidavit must be signed by an official representative of the applicant who is authorized to sign and submit this application on the applicant's behalf.

This application is hereby submitted on behalf of the Applicant identified herein. I attest the foregoing application has been completed truthfully and accurately to the best of my knowledge and belief. I am making this affidavit knowing that any false statements or material omission may subject me or the entity identified herein to criminal penalties for making a false affidavit under Section 575.050, RSMo.

The applicant agrees to comply with all applicable federal and state law(s), all applicable rules/regulations of the Board, Rx Cares for Missouri Program requirements, and all applicable Medsafe® Program requirements. I hereby certify under penalty of perjury that the information and answers contained in this application and any attachments are true and correct to the best of my knowledge and belief.

SIGNATURE OF APPLICANT	TITLE
PRINT NAME	DATE

Emergency Rules

**Title 20—DEPARTMENT OF INSURANCE,
FINANCIAL INSTITUTIONS AND PROFESSIONAL
REGISTRATION**

**Division 2220—State Board of Pharmacy
Chapter 2—General Rules**

EMERGENCY RULE

20 CSR 2220-2.990 Rx Cares For Missouri Program

PURPOSE: This rule establishes the Missouri Board of Pharmacy’s medication disposal program as part of the Rx Cares for Missouri Program created by section 338.710, RSMo, and establishes standards/criteria for Program operation and participation.

EMERGENCY STATEMENT: The nation and the state of Missouri continues to grapple with the opioid epidemic that has resulted in unprecedented deaths in Missouri and nationwide. The United States Centers for Disease Control and Prevention has declared a national opioid epidemic and has urged states to take proactive measures to decrease the availability and use of opioid medication to protect lives. Missouri Executive Order 17-18 was subsequently issued which declared “Missouri is facing a public health crisis of epidemic proportions from the unlawful distribution and misuse of opioids.” The Executive Order further provided the opioid epidemic “poses a grave danger to Missouri.” Although significant efforts have been made to address the opioid abuse, the Director of the Missouri Department of Health and Human Services issued a statement on June 27, 2018, indicating that “the opioid crisis is the number one public health issue Missouri is facing.”

One of the factors contributing to the opioid abuse is the availability of unused, unwanted, or excess controlled substances in a patient’s possession. According to the U.S. Drug Enforcement Administration, the collection and destruction of unwanted/unused medication can help prevent opioid addiction, overdoses, and deaths by keeping unused pain medicine out of the wrong hands. In 2018, the Missouri General Assembly approved appropriation for the Missouri Board of Pharmacy for the Rx Cares for Missouri Program which was established to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri (section 338.710, RSMo). In alignment with this goal, the board solicited vendors to operate a statewide controlled substance collection program that would allow Missouri citizens to securely dispose of unwanted controlled substances at board funded collection sites. The competitive bidding vendor/contracting process was completed in April 2019 and an approved vendor contract awarded by the Missouri Office of Administration in May 2019. The board is proposing this emergency rule to establish the necessary requirements for the implementation and operation of the statewide controlled substance collection/destruction program.

*The board has determined this emergency rule is needed to protect Missouri patients by establishing a statewide program for the collection and disposal of unwanted/unused controlled substances to prevent opioid deaths, overdoses, and abuse. Absent an emergency rule to implement the Rx Cares for Missouri Program, the board would be unable to implement the statewide collection program and dangerous controlled drugs may continue to be easily accessible throughout the state. As a result, the Missouri State Board of Pharmacy finds there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri and United States Constitutions**. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed July 18, 2019, becomes effective July 28,*

2019, and expires February 27, 2020.

(1) Section 338.710, RSMo, established the “Rx Cares for Missouri Program” within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri. As part of the Rx Cares for Missouri Program, the board is hereby establishing a medication destruction and disposal program (the “Program”) for the purposes of collecting unused or unwanted medication from the public for disposal in accordance with state and federal law. Operation of the Program may be delegated to a board approved vendor or third-party.

(2) Eligible Participants. To be eligible for participation, applicants must be physically located in Missouri and currently registered to collect unwanted controlled substances with the United States Drug Enforcement Administration (“DEA”) and the Missouri Bureau of Narcotics and Dangerous Drugs (“BNDD”) unless exempt from registration by state or federal law. Additionally, the applicant must be—

(A) A licensed Missouri pharmacy or drug distributor;

(B) A licensed healthcare provider authorized to prescribe controlled substances;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or

(E) A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education.

(3) Participant Requirements. Approved participants must establish and operate a public medication collection program in compliance with Program requirements, including, but not limited to, all applicable board or vendor requirements for collecting, submitting, or forwarding medication for destruction and disposal. Participants must promptly enroll in the program after notification of approval is received from the board.

(A) Subject to appropriation, approved Program participants will be provided a collection receptacle and inner liners to be used for collecting medication pursuant to the Program. Participants may alternatively use an existing collection receptacle if approved by the board or the Program vendor. Program participants are responsible for installation of the collection receptacle in accordance with vendor requirements.

(B) Collection receptacles must be physically located in the state of Missouri at an address approved by the board. A board approved sign must be located on or near the receptacle indicating that the collection program has been funded by the Missouri Board of Pharmacy as part of the Rx Cares for Missouri Program. Collection receptacles may not be used to dispose of medication from the pharmacy’s inventory.

(C) Medication must be collected and handled in compliance with all state and federal controlled substance laws. Program participants may submit collected medication to the vendor or the vendor’s authorized designee for disposal at no cost to the participant up to twelve (12) times per participation year. Program participants may arrange for additional medication disposal at the participant’s cost.

(D) Program participants shall notify the board in writing within ten (10) days after ceasing or terminating Program participation. Unless otherwise agreed by the board for good cause, Program participants shall reimburse the board for the cost of the collection receptacle if the participant fails to actively maintain and operate a collection program during the participation year. Collection receptacle costs must be remitted to the board within sixty (60) days after notification from the board.

(4) Application Procedures. Applications to participate in the

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Program must be submitted to the board on a board approved form and include—

(A) The applicant's name, address, contact telephone number, and e-mail address;

(B) The Missouri address where the collection receptacle will be located;

(C) A copy of the applicant's DEA and BNDD controlled substance collector registrations;

(D) A description of how the medication collection program will be operated, including operational times and how the program will be advertised to the public;

(E) A designation of whether the applicant will be using a board approved collection receptacle or supplying their own collection receptacle subject to vendor approval; and

(F) A description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.

(5) Approval Criteria. At the discretion of the board, applicants will be approved for Program participation subject to funding availability. Participation approval shall be valid for one (1) calendar year. The following criteria will be considered by the board when reviewing applications:

(A) The need for a medication collection program in the proposed collection site area, including, but not limited to, any alternative collection programs/opportunities available;

(B) Relevant evidence or data regarding drug use, abuse, fatalities, or trends;

(C) The number of applications submitted or previously approved by the board for the applicant regardless of collection site;

(D) The nature and structure of the proposed collection program, including, but not limited to, operational times and any public restrictions;

(E) Available staff, resources, or expertise;

(F) Any state, federal, or local disciplinary action, including any pending board complaints or investigations;

(G) The applicant's compliance with state and federal drug and controlled substance laws;

(H) The applicant's financial need and available resources; and

(I) Any other factor that may be relevant to the applicant's ability to participate in or comply with the Program.

(6) Information Sharing. As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to—

(A) The board or the board's authorized designee on request; and

(B) The Missouri Governor and the Missouri General Assembly pursuant to section 338.710, RSMo.

AUTHORITY: sections 338.140 and 338.280, RSMo 2016, and sections 338.142 and 338.710, RSMo Supp. 2018. Emergency rule filed July 18, 2019, effective July 28, 2019, expires Feb. 27, 2020. An emergency rule and a proposed rule covering this same material will be published in the September 2, 2019, issue of the Missouri Register.

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parties, the presiding officer shall certify to the Administrator the record, which shall contain the transcript of testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, the presiding officer's report, and any exceptions thereto which may have been filed by the parties.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.66 Exceptions.

(a) Within twenty days after the date upon which a party is served a copy of the report of the presiding officer, such party may file with the Hearing Clerk, Office of the Administrative Law Judge, exceptions to the recommended decision, findings of fact and conclusions of law contained in the report. The party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.

(b) The Hearing Clerk shall cause such filings to become part of the record of the proceeding.

(c) The Administrative Law Judge may, upon the request of any party to a proceeding, grant time beyond the twenty days provided in paragraph (a) of this section for the filing of a response to the exceptions filed by another party if he determines that no party in the hearing will be unduly prejudiced and that the ends of justice will be served thereby. Provided however, that each party shall be entitled to only one filing under this section; that is, either a set of exceptions or a response thereto.

[44 FR 55332, Sept. 26, 1979]

§ 1316.67 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect,

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which date shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which event the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

[44 FR 42179, July 19, 1979, as amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.68 Copies of petitions for judicial review.

Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Administrator in quintuplicate. The Administrator shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals.

[36 FR 7820, Apr. 24, 1971. Redesignated at 44 FR 42179, July 19, 1979]

PART 1317—DISPOSAL

Sec.

1317.01 Scope.

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1317.35 Collection by law enforcement.

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1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.

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Subpart C—Destruction of Controlled Substances

1317.90 Methods of destruction.
1317.95 Destruction procedures.

AUTHORITY: 21 U.S.C. 821, 822, 823, 827, 828, 871(b), and 958.

SOURCE: 79 FR 33565, Sept. 9, 2014, unless otherwise noted.

§ 1317.01 Scope.

This part sets forth the rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

Subpart A—Disposal of Controlled Substances by Registrants**§ 1317.05 Registrant disposal.**

(a) *Practitioner inventory.* Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

(i) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.

(ii) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:

(A) By transfer to a registrant authorized to transport or destroy the substance;

(B) By delivery to an agent of the Administration or to the nearest office of the Administration; or

(C) By destruction in the presence of an agent of the Administration or other authorized person.

(5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

(b) *Non-practitioner inventory.* Any registrant that is a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: The registered person from whom it was obtained, the

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registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (b)(3) of this section.

(i) If a non-practitioner transports controlled substances by its own means to an unregistered location for destruction, the non-practitioner shall do so in accordance with the procedures set forth at §1317.95(c).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any authorized purpose, transportation shall be directly to the authorized registered location and two employees of the transporting non-practitioner shall accompany the controlled substances to the registered destination location. Directly transported means the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur.

(c) *Collected controlled substances.* Any collector in lawful possession of a controlled substance acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

(1) *Mail-back program.* Upon receipt of a sealed mail-back package, the collector shall promptly:

(i) Destroy the package in accordance with subpart C of this part using an on-site method of destruction; or

(ii) Securely store the package and its contents at the collector's registered location in a manner consistent with §1301.75(c) of this chapter (for practitioners), or in a manner consistent with the security requirements for Schedule II controlled substances (for non-practitioners) until prompt on-site destruction can occur.

(2) *Collection receptacles.* Upon removal from the permanent outer con-

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tainer, the collector shall seal it and promptly:

(i) Destroy the sealed inner liner and its contents;

(ii) Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with §1301.75(c) of this chapter (for practitioners), or in a manner consistent with §1301.72(a) of this chapter (for non-practitioners) until prompt destruction can occur; or

(iii) Securely store the sealed inner liner and its contents at a long-term care facility in accordance with §1317.80(d).

(iv) *Practitioner methods of destruction.* Collectors that are practitioners (*i.e.*, retail pharmacies and hospitals/clinics) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (a)(1), (a)(2), or (a)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the collector's authorized collection location.

(v) *Non-practitioner methods of destruction.* Collectors that are non-practitioners (*i.e.*, manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (b)(1), (b)(2), or (b)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall.

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with the information required of manufacturers in §1304.22(a)(2)(iv) of this chapter.

(b) Each registrant that delivers a controlled substance in Schedule I or II for the purpose of return or recall shall use an order form in the manner described in part 1305 of this chapter.

(c) Deliveries for the purpose of return or recall may be made through a

freight forwarding facility operated by the person to whom the controlled substance is being returned provided that advance notice of the return is provided and delivery is directly to an agent or employee of the person to whom the controlled substance is being returned.

§ 1317.15 Reverse distributor registration requirements and authorized activities.

(a) Any person that reverse distributes a controlled substance shall be registered with the Administration as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.

(b) A reverse distributor shall acquire controlled substances from a registrant pursuant to §§ 1317.05 and 1317.55(a) and (c) in the following manner:

(1) Pick-up controlled substances from a registrant at the registrant's registered location or authorized collection site; or

(2) Receive controlled substances delivered by common or contract carrier or delivered directly by a non-practitioner registrant.

(i) Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once en route, such deliveries may not be re-routed to any other location or person, regardless of registration status.

(ii) All controlled substance deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.

(c) Upon acquisition of a controlled substance by delivery or pick-up, a reverse distributor shall:

(1) Immediately store the controlled substance, in accordance with the security controls in parts 1301 and 1317 of this chapter, at the reverse distributor's registered location or immediately transfer the controlled substance to the reverse distributor's registered location for secure storage, in accordance with the security controls in parts 1301 and 1317 of this chapter, until timely destruction or prompt return of the controlled substance to the

registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

(2) Promptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(3) Timely destroy the controlled substance in a manner authorized in subpart C of this part.

(d) A reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.

Subpart B—Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants

§ 1317.30 Authorization to collect from non-registrants.

(a) The following persons are authorized to collect controlled substances from ultimate users and other non-registrants for destruction in compliance with this chapter:

(1) Any registrant authorized by the Administration to be a collector pursuant to § 1317.40; and

(2) Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35.

(b) The following non-registrant persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may transfer that substance to the authorized persons listed in paragraph (a) of this section, and in a manner authorized by this part, for the purpose of disposal:

(1) An ultimate user in lawful possession of a controlled substance;

(2) Any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance; and

(3) A long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance, in accordance with § 1317.80 only.

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§ 1317.35 Collection by law enforcement.

(a) Federal, State, tribal, or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property using the following collection methods:

(1) Take-back events in accordance with § 1317.65;

(2) Mail-back programs in accordance with § 1317.70; or

(3) Collection receptacles located inside law enforcement's physical address.

(b) Law enforcement that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(c) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(d) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for transferring illicit controlled substances.

(e) Law enforcement that transfers controlled substances collected from ultimate users pursuant to this part to a reverse distributor for destruction should maintain a record that contains the following information: If a sealed inner liner as described in § 1317.60 is used, the unique identification number of the sealed inner liner transferred, and the size of the sealed inner liner transferred (e.g., 5-gallon, 10-gallon, etc.); if a mail-back package as described in § 1317.70 is used, the unique identification number of each package; the date of the transfer; and the name,

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address, and registration number of the reverse distributor to whom the controlled substances were transferred.

§ 1317.40 Registrants authorized to collect and authorized collection activities.

(a) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with § 1301.51 of this chapter. Authorization to be a collector is subject to renewal. If a registrant that is authorized to collect ceases activities as a collector, such registrant shall notify the Administration in accordance with § 1301.52(f) of this chapter.

(b) Collection by registrants shall occur only at the following locations:

(1) Those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and

(2) Long-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles.

(c) Collectors may conduct the following activities:

(1) Receive and destroy mail-back packages pursuant to § 1317.70 at an authorized registered location that has an on-site method of destruction;

(2) Install, manage, and maintain collection receptacles located at their authorized collection location(s) pursuant to §§ 1317.75 and 1317.80; and

(3) Promptly dispose of sealed inner liners and their contents as provided for in § 1317.05(c)(2).

§ 1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.

(a) A reverse distributor is authorized to acquire controlled substances from law enforcement that collected the substances from ultimate users. A reverse distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

(b) A distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§ 1317.75 and 1317.80.

(c) A reverse distributor or a distributor that acquires controlled substances in accordance with paragraph (a) or (b) of this section shall:

(1) Acquire the controlled substances in the manner authorized for reverse distributors in § 1317.15(b)(1) and (2);

(2) Dispose of the controlled substances in the manner authorized for reverse distributors § 1317.15(c) and (d); and

(3) Securely store the controlled substances in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur.

§ 1317.60 Inner liner requirements.

(a) An inner liner shall meet the following requirements:

(1) The inner liner shall be waterproof, tamper-evident, and tear-resistant;

(2) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

(3) The contents of the inner liner shall not be viewable from the outside when sealed;

(4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and

(5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

(b) Access to the inner liner shall be restricted to employees of the collector.

(c) The inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.65 Take-back events.

(a) Federal, State, tribal, or local law enforcement may conduct a take-back event and collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property in accordance with this section. Any person may

partner with law enforcement to hold a collection take-back event in accordance with this section.

(b) Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take-back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.

(c) Each take-back event should have at least one receptacle for the collection of controlled substances. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner as specified in § 1317.60 of this chapter. The outer container should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.

(d) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

§ 1317.70 Mail-back programs.

(a) A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with § 1317.90 of this chapter.

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(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(c) Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. The packages made available shall meet the following specifications:

(1) The package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;

(2) The package shall be water- and spill-proof; tamper-evident; tear-resistant; and sealable;

(3) The package shall be preaddressed with and delivered to the collector's registered address or the participating law enforcement's physical address;

(4) The cost of shipping the package shall be postage paid;

(5) The package shall have a unique identification number that enables the package to be tracked; and

(6) The package shall include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

(d) Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when mailing back controlled substances to a collector. The collector or law enforcement may implement a system that al-

lows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or law enforcement that they are sending one of the designated packages by giving the unique identification number on the package.

(e) A collector that conducts a mail-back program pursuant to paragraph (a) shall:

(1) Accept only those controlled substances contained within packages that the collector made available for the collection of controlled substances by mail and packages that are lawfully forwarded to the collector pursuant to paragraph (e)(3) of this section.

(2) Within three business days of receipt, notify the Field Division Office of the Administration in their area of the receipt of a package that likely contains controlled substances that the collector did not make available or did not agree to receive pursuant to subparagraph (e)(3) of this section.

(3) When discontinuing activities as a collector or ceasing an authorized mail-back program:

(i) Make a reasonable effort to notify the public prior to discontinuing such activities or ceasing the authorized mail-back program; and

(ii) Obtain the written agreement of another collector that has and utilizes at its registered location a method of destruction consistent with §1317.90 of this chapter to receive all remaining mail-back packages that were disseminated but not returned and arrange for the forwarding of only such packages to that location.

(f) Only law enforcement officers employed by the law enforcement agency or law enforcement component of a Federal agency and employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§ 1317.75 Collection receptacles.

(a) Collectors or Federal, State, tribal, or local law enforcement may manage and maintain collection receptacles for disposal.

(b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

(c) Collectors shall only allow ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V to deposit such substances in a collection receptacle at a registered location. Collectors shall not permit an ultimate user to transfer such substance to any person for any reason. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.

(d) Collection receptacles shall be securely placed and maintained:

(1) Inside a collector's registered location, inside law enforcement's physical location, or at an authorized long-term care facility;

(2) At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter). Except as follows:

(i) At a hospital/clinic: A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided;

(ii) At a narcotic treatment program: A collection receptacle shall be located in a room: That does not contain any other controlled substances and is securely locked with controlled access;

(iii) At a long-term care facility: A collection receptacle shall be located in a secured area regularly monitored by long-term care facility employees.

(e) A controlled substance collection receptacle shall meet the following design specifications:

(1) Be securely fastened to a permanent structure so that it cannot be removed;

(2) Be a securely locked, substantially constructed container with a permanent outer container and a re-

movable inner liner as specified in §1317.60 of this chapter;

(3) The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;

(4) The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

(f) Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.

(g) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.

§ 1317.80 Collection receptacles at long-term care facilities.

(a) A long-term care facility may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such long-term care facility by transferring those controlled substances into an authorized collection receptacle located at that long-term care facility. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

(b) Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and

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maintain collection receptacles at long-term care facilities and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities. Collectors authorized to install, manage, and maintain collection receptacles at long-term care facilities shall comply with all requirements of this chapter, including §§ 1317.60, 1317.75, and 1317.80.

(c) The installation, removal, transfer, and storage of inner liners shall be performed either: By or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector; or, by or under the supervision of two employees of the authorized collector.

(d) Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with § 1317.05(c)(2)(iv).

(e) Neither a hospital/clinic with an on-site pharmacy nor a retail pharmacy shall operate a collection receptacle at a long-term care facility until its registration has been modified in accordance with § 1301.51 of this chapter.

§ 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

(a) In the event of a product recall, an ultimate user in lawful possession of a controlled substance listed in Schedule II, III, IV, or V may deliver the recalled substance to the manufacturer of the substance or another registrant authorized by the manufacturer to accept recalled controlled substances on the manufacturer's behalf.

(b) An ultimate user who is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j) and wishes to deliver any unused controlled substances received as part of that research to the registered dispenser from which the ultimate user obtained those substances may do so in accordance with regulations promul-

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gated by the Secretary of Health and Human Services pursuant to 21 U.S.C. 355(i) and 360b(j).

Subpart C—Destruction of Controlled Substances

§ 1317.90 Methods of destruction.

(a) All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to § 1317.95(c), shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

(b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.

(c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

§ 1317.95 Destruction procedures.

The destruction of any controlled substance shall be in accordance with the following requirements:

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction.* If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

(b) *Transport to a registered location.* If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed:

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(1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete;

(c) *Transport to a non-registered location.* If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed:

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

(4) Two employees of the transporting registrant shall handle or observe the handling of any controlled

substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

(d) *On-site destruction.* If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed:

(1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

PART 1321—DEA MAILING ADDRESSES

Sec.

1321.01 DEA mailing addresses.

AUTHORITY: 21 U.S.C. 871(b).

SOURCE: 75 FR 10685, Mar. 9, 2010, unless otherwise noted.

§ 1321.01 DEA mailing addresses.

The following table provides information regarding mailing addresses to be used when sending specified correspondence to the Drug Enforcement Administration.

TABLE OF DEA MAILING ADDRESSES

Code of Federal Regulations Section—Topic	DEA Mailing address
DEA Administrator	
1308.43(b)—Petition to initiate proceedings for rulemaking	Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, VA 22152.
316.23(b)—Petition for grant of confidentiality for research subjects.	
1316.24(b)—Petition for exemption from prosecution for researchers.	
1316.48—Notice of appearance.	
DEA Office of Diversion Control	
1301.52(c)—Controlled substances registration return for cancellation	Drug Enforcement Administration, Attn: Office of Diversion Control/OD, 8701 Morrisette Drive, Springfield, VA 22152.
1307.03—Exception request filing.	
1307.22—Disposal of controlled substances by the Administration delivery application.	
1308.21(a)—Exclusion of nonnarcotic substance.	
1308.23(b)—Exemption for chemical preparations.	
1308.25(a)—Exclusion of veterinary anabolic steroid implant product application.	
1308.31(a)—Exemption of a nonnarcotic prescription product application.	
1308.33(b)—Exemption of certain anabolic steroid products application.	
1310.13(b)—Exemption for chemical preparations.	

DISPOSAL REGULATIONS: REGISTRANT FACT SHEET

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 (“Disposal Act”). The final rule is available for public view at <http://www.federalregister.gov/public-inspection>. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on <http://www.regulations.gov>, and our website, <http://www.DEAdiversion.usdoj.gov>. This Registrant Fact Sheet contains a general summary of some of the effects of the new rule on registrants. For detailed information, please visit our website or contact your local DEA office.

1. What is the Disposal Act?

- The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

2. What do the implementing regulations do?

- Effective October 9, 2014, the implementing regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.
- The new regulations reorganize and consolidate previously existing regulations on disposal, including the role of reverse distributors. Effective October 9, 2014, the existing regulation on disposal of controlled substances, 21 C.F.R. 1307.21, will be removed. New requirements on proper disposal procedure and security will be in a new part 1317.
- As of October 9, 2014, all Memoranda of Agreement (MOA) and Memoranda of Understanding (MOU) issued pursuant to current 21 C.F.R. 1307.21 will be null and void. Registrants should consult 21 C.F.R. 1317.05(a) for information on new MOAs and MOUs for the disposal of controlled substances.
- Effective October 9, 2014, the existing regulation on return and recall, 21 C.F.R. 1307.12, will be removed. New return and recall requirements for registrants and non-registrants are incorporated into new 21 C.F.R. 1317.10 and 1317.85.
- Effective October 9, 2014, registrants must use DEA Form 41 to record the destruction of controlled substances. However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as “drug wastage” and “pharmaceutical wastage”). Such remaining substance must be properly recorded, stored, and

destroyed in accordance with DEA regulations (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

3. Who is an “ultimate user”?

- The CSA defines an “ultimate user” as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

4. What is “collection”?

- “Collection” means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent’s property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term “collector” means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

5. How can a registrant become an “authorized collector”?

- Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at <http://www.DEAdiversion.usdoj.gov>. Once authorized, these entities are “authorized collectors.”
- Eligible registrants must have authority to handle schedule II controlled substances.
- Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

6. Who can operate a collection receptacle for the collection of pharmaceutical controlled substances?

- Authorized collectors may maintain collection receptacles inside their registered location; and Federal, State, tribal, or local law enforcement may continue to maintain collection receptacles inside their physical location.
- Authorized hospitals/clinics with an on-site pharmacy, and retail pharmacies, may maintain collection receptacles at long-term care facilities.

7. Who can operate a mail-back program for the collection of pharmaceutical controlled substances?

- Authorized collectors with an on-site method of destruction may operate a mail-back program.

8. If I become an authorized collector and decide to stop, how do I do so?

- *Collection receptacle:* Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical controlled substances in their possession in accordance with the new rule, and notify the DEA that collection activities are ceasing, in writing or online at <http://www.DEAdiversion.usdoj.gov>.

- *Mail-back program:* Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and notify the DEA that collection activities are ceasing, in writing or online at <http://www.DEAdiversion.usdoj.gov>.

9. What can I collect as an authorized collector?

- An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.
- Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (*i.e.*, registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

10. Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?

- No. Ultimate users may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

11. I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?

- No. A collector shall not require any person to provide any personally identifying information.

12. How does a registrant dispose of controlled substances when 21 C.F.R. 1307.21 is removed?

- The authorized methods and procedures regarding disposal are outlined, in 21 C.F.R. 1317.05, according to whether the substances being disposed of are practitioner inventory, non-practitioner inventory, or collected controlled substances.

13. How can a registrant destroy controlled substances?

- The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceutical controlled substances must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.
- "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.



Rules of Department of Health and Senior Services

Division 30—Division of Regulation and Licensure Chapter 1—Controlled Substances

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(I) A copy of the applicant's collaborative or supervision agreements with physicians, and a list of controlled substances from each physician that the mid-level practitioner is authorized to conduct activities with, in that agreement;

(J) The applicant's street address, city, zip code, county, and state of the applicant's primary, principle practice location. This will be the principle address that appears on the controlled substances registration. Post office boxes shall not be accepted. Applicants shall also provide any secondary practice location addresses and the number of hours worked per week for each location for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs the applicant;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31,*

2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.019 Registration Location

PURPOSE: This rule establishes requirements for the physical location of a registration.

(1) A controlled substance registration shall be issued at a U.S. Postal Service street address.

(2) A controlled substance registration shall be issued to an individual practitioner at a Missouri practice location where controlled substance and other patient care activities occur.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.020 List of Excepted Substances

(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo Supp. 1989. This rule was previously filed as 13 CSR 50-130.020. Original rule filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed Nov. 14, 1978, effective Dec. 11, 1978. Amended: Filed Oct. 12, 1979, effective Nov. 11, 1979. Amended: Filed Oct. 14, 1981, effective Nov. 2, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed Oct. 2, 1991, effective Feb. 6, 1992. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.023 Registration Changes

PURPOSE: This rule establishes procedures for modifying an existing registration, describes the conditions under which a registration automatically terminates, and prohibits the transfer of a registration.

(1) Modification of Registration.

(A) Any registrant may apply to modify his/her registration to authorize the handling of controlled substances in additional schedules by submitting a request in writing to the

department. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

(B) Any registrant may request to modify his or her name or address as shown on the registration provided that such a modification does not constitute a change of ownership or location. The request shall be made in writing and no fee shall be required to be paid for the modification. The request for changes may be submitted electronically using the department's online database system. Requests submitted in paper form shall contain the registrant's signature.

(C) When the registrant's name or address as shown on the registration changes, the registrant shall notify the Department of Health and Senior Services in writing, including the registrant's signature, prior to or within thirty (30) days subsequent to the effective date of the change. No fee shall be required to be paid for the modification.

(D) Collector of Unwanted Controlled Substances. A current registrant with the department may request to have their registration modified to authorize the collection of unwanted controlled substances. Requests shall be submitted in writing to the Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO, 65102-0570. Requests shall provide the requesting registrant's name, address, and current Missouri Controlled Substances Registration number. Requests shall identify the method of collection such as either a collection receptacle box or mail-back return system, or both, and shall identify the exact physical address of the receptacle. Collection receptacles located in long term care facilities shall be maintained by a retail pharmacy or a hospital/clinic with an on-site pharmacy. The bureau will respond to the registrant's request in writing. Registrants authorized by the department to collect unwanted controlled substances shall comply with all requirements for record keeping and security in accordance with federal regulations. The privilege of being a collector may be terminated if the registrant's authority to collect is terminated by the United States Drug Enforcement Administration, a judicial order, an act by a state licensing board or agency, or if the collector's registration is restricted as a matter of public discipline by the department. An authorized collector who wishes to cease being a collector shall notify the bureau in writing of the date that collections will cease.

(2) Termination of Registration.

(A) The registration of any person shall terminate—

1. On the expiration date assigned to the registration at the time the registration was



issued;

- 2. If and when the person dies;
- 3. If and when the person ceases legal existence;
- 4. If and when a business changes ownership, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the new owner applies for a registration within the thirty- (30-) day period and the corresponding Drug Enforcement Administration registration remains effective as provided for by the Drug Enforcement Administration;

5. If and when the person discontinues business or changes business location, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the person applies for a new registration or modification within the thirty- (30-) day period; or

6. Upon the written request of the registrant.

(B) A mid-level practitioner's registration shall be contingent upon the physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, having a current and valid registration. When such physician's registration expires, closes, or is no longer valid, any mid-level practitioner(s) with whom he or she has entered into an agreement shall no longer have controlled substance authority. The mid-level practitioner(s) shall cease controlled drug activities until the physician has obtained a new registration or the mid-level practitioner(s) obtain(s) another agreement with another physician pursuant to Chapter 334, RSMo. Mid-level practitioners and any physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, shall notify the Department of Health and Senior Services of the termination of any such agreement.

(C) Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Department of Health and Senior Services of the effective date of this action and promptly return his/her registration certificate to the Department of Health and Senior Services.

(3) Transfer of Registration. No registration or any authority conferred by registration shall be assigned or otherwise transferred.

AUTHORITY: section 195.195, RSMo Supp. 2018. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expired March 25,*

2019. Amended: Filed Sept. 17, 2018, effective March 30, 2019.

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.025 List of Exempt Anabolic Steroid Products
(Rescinded November 30, 2000)

AUTHORITY: section 195.015.4, RSMo Supp. 1989. Original rule filed July 6, 1993, effective Dec. 9, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.026 Separate Registrations

PURPOSE: This rule defines the requirements for controlled substance registrations for separate activities and for separate sites, and defines when a separate registration is not required.

(1) Independent Activities. The following eight groups of activities are deemed to be independent of each other and require separate registration:

- (A) Manufacturing controlled substances;
- (B) Distributing controlled substances, except:

1. A dispenser distributing less than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year shall be exempt from obtaining a separate registration for distributing;

2. A dispenser distributing more than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year must obtain a separate registration as a distributor but shall be exempt from maintaining separate inventories under 19 CSR 30-1.042;

(C) Dispensing controlled substances listed in Schedules II-V;

(D) Conducting research and instructional activities with controlled substances listed in Schedule I;

(E) Conducting research with controlled substances listed in Schedules II-V;

(F) Conducting a narcotic treatment program with narcotic controlled substances listed in Schedules II-V;

(G) Conducting instructional activities with controlled substances listed in Schedules II-V;

(H) Importing controlled substances;

(I) Exporting controlled substances;

(J) Conducting chemical analysis with controlled substances listed in any schedule.

(2) No activity shall be conducted with any controlled substance in any schedule not requested for and shown on the current registration.

(3) Separate Locations. A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(A) For purposes of registration only, the following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

1. A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registrants other than the registered person or to persons not required to register;

2. An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains these substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders;

3. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at the office and where no supplies of controlled substances are maintained;

4. A location on the immediate or contiguous property of a hospital, provided that the location is owned and operated by the hospital and controlled substances are not dispensed for use away from the location;

5. A separate location from a registered pre-hospital emergency medical service location where an emergency vehicle is housed that does not have a permanent location of operation and which rotates between locations at least every 30 days for operational reasons other than controlled substance registration;

6. A pre-hospital emergency medical service located outside the state of Missouri that renders assistance to a pre-hospital emergency medical service located in the state of Missouri under a mutual aid contract in the case of an emergency, major catastrophe or other unforeseen event that jeopardizes the ability of the local Missouri pre-hospital emergency medical service to promptly respond.

(B) A separate registration is not required for each separate practice location for an individual practitioner who has a temporary location registration.



3. It shall be the responsibility of each agency’s administrator, chief, sheriff, or other chief executive officer to insure—

A. Only authorized employees have access to the database;

B. Employees only use their own passwords and passwords are not shared;

C. Each employee adheres to all state and federal laws regarding confidentiality; and

D. As employees change, that new passwords are assigned to new employees and passwords of ex-employees or transferred employees are removed. The chief, sheriff, or chief executive officer of the law enforcement or regulatory agency shall notify the DHSS in writing when an employee’s access is to be added or removed; and

(O) Method for Enforcement Agencies to Gain or Alter Access to the Database.

1. Requests submitted to the DHSS to add or remove an employee from access to the database shall—

A. Be submitted in writing on the agency’s letterhead;

B. State whether this is a request for an employee to be granted access to the database or a request to remove an employee’s access;

C. Provide the employee’s full name and title;

D. Provide the employee’s Missouri POST certification number if the employee is a sworn law enforcement officer; and

E. Be signed by the chief, sheriff, or chief executive officer of the requesting agency.

2. Multiple requests for multiple employees and actions may be submitted on one (1) letter.

3. The DHSS shall notify the provider of the database in writing of persons who are given access or have access removed.

4. The DHSS may restrict access to the database to a limited number of people in each agency, depending on the size of the agency, their locations, and number of sworn officers engaged in the actual enforcement of controlled substance laws.

AUTHORITY: sections 195.017 and 195.417, RSMo Supp. 2010 and sections 195.030, 195.050, and 195.195, RSMo 2000.* Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006. Emergency amendment filed July 9, 2010, effective Sept. 28, 2010, expired March 26, 2011. Amended: Filed June 29, 2010, effective Jan. 30, 2011.

*Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005, 2006, 2008; 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993; and 195.417, RSMo 2001, amended 2003, 2005, 2008.

19 CSR 30-1.076 Emergency Distribution by a Pharmacy

PURPOSE: This rule provides for dispensing of controlled substances by a pharmacy in emergency situations.

(1) An emergency means a situation where a quantity of a controlled substance must be dispensed by a pharmacy to a patient who does not have an alternative source for that substance reasonably available to him/her and the pharmacy cannot obtain that substance through its normal distribution channels within the time required to meet the immediate needs of the patient for that substance. In the event of an emergency, a pharmacy may distribute (without being registered as a distributor) a controlled substance in Schedule III, IV or V to a second pharmacy in order for that pharmacy to dispense the substance; provided, that—

(A) The amount distributed does not exceed the amount required by the second pharmacy for his/her immediate dispensing;

(B) The distribution is recorded as being dispensed by the first pharmacy and the second pharmacy records the substance as being received. Each pharmacy will retain a signed receipt of the distribution;

(C) The second pharmacy is registered to dispense the controlled substance to be distributed to him/her;

(D) If the substance is a Schedule II controlled substance, the official order form designated by the federal Drug Enforcement Administration must be used to document the transfer.

AUTHORITY: section 195.195, RSMo 1994.* Original rule filed April 14, 2000, effective Nov. 30, 2000.

*Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.

19 CSR 30-1.078 Disposing of Unwanted Controlled Substances

PURPOSE: This rule establishes procedures for disposing of unwanted controlled substances.

(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) Retain a DEA Form 41 in compliance with federal regulations;

(D) Become an Authorized Collector of Controlled Substances. Registrants shall dispose of all unwanted controlled substances and keep records in accordance with federal regulations. Only manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, 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;

(E) Contact the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Health and Senior Services for information pertaining to subsections (1)(A), (B), (C) or (D) of this rule.

(2) Destruction of controlled substances 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 maintains a DEA Form 41 in compliance with federal regulation. 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 patient care area of a hospital with an on-site pharmacy, 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 and completed 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, the witness, is not required to be a licensed medical professional, but must be



an employee of the registrant, unless 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 (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, have been removed from their original or security packaging, 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, have been removed from their original or security packaging, 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) Collection Receptacle Boxes and Mail-Back Programs for Patients' Unwanted Controlled Substance Prescriptions.

(A) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies 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; or upon a discontinuation of use authorized by a prescriber; or upon the death of a patient.

(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 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 Supp. 2018. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expired March 25, 2019. Amended: Filed Sept. 17, 2018, effective March 30, 2019.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989, 2014 and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

MEDSAFE POLICY (PHARMACY)

For Participants in the Rx Cares for Missouri program funded by the Missouri Board of Pharmacy ("Participant")



Participant agrees to adopt the following Policy:

- a) Once Participant becomes an Authorized Collector, Participant agrees to install and manage MedSafe Collection Receptacles within the immediate proximity of a designated area where controlled substances are stored and at which an employee is present in compliance with DEA Regulations on disposal of controlled substances. Disposal of a pharmaceutical controlled substance in Schedules II, III, IV and V into the MedSafe Collection Receptacle may only be performed by ultimate users. Authorized Collectors may only view what ultimate users deposit into the MedSafe Collection Receptacle and they may ask what substances are being deposited. The Participant cannot use the Collection Receptacle to dispose of unused controlled substances in their inventory or stock.
- b) Participant agrees to follow DEA Regulations related to unlocking the Collection Receptacle and removing the MedSafe Inner Liner. The installation, removal, transfer and storage of the MedSafe Inner Liners shall be performed by or under the supervision of two employees of the Authorized Collector.
- c) Participant agrees to replace Inner Liner at the established frequency interval, seal Inner Liner in accordance with included instructions for use and provide to the selected common carrier (UPS) for prepaid return transportation to the treatment facility. Upon removal, sealed Inner Liners will be securely stored at the Authorized Collector's registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer. Participant shall maintain all records as required by DEA regulations.
- d) Participant agrees to display The Missouri Board of Pharmacy and Sharps-approved program signage above the Collection Receptacle.
- e) Participant shall keep confidential any document, information, process, practice, handling method, contract, or agreement provided by Sharps in connection with the MedSafe Program, except whatever is expressly allowed by Sharps.
- f) Participant agrees to only use MedSafe Inner Liners provided by Sharps Compliance, which are designed to work with the MedSafe Collection Receptacle to meet DEA and DOT regulations for collection and disposal of patient and consumer dispensed or expired medications including controlled substances. Pursuant to the Rx Cares for Missouri Program, Participant will be provided twelve (12) inner liners at no cost to the Participant. If further participation in the MedSafe program is desired, the Participant agrees to assume financial responsibility for the purchase of additional four-packs of MedSafe Inner Liners from Sharps Compliance (800) 772-5657 or emailing orders@sharpsinc.com.
- g) Participant agrees to comply with MedSafe Returns and Product Warranty Policy Service Provider warrants that all MedSafe systems are designed to meet all applicable state and federal regulations and are free from defect in material and workmanship when used in accordance with instructions and for their designed purpose for a period of one year from date of purchase. In the event that Participant makes any modifications to the Systems, or if the Participant does not utilize the System in strict accordance with the Instructions for Use (included with the System) or the System is damaged due to the acts or omissions of the Participant or its employees, then the foregoing warranty shall be void and null and Service Provider will have no further liability there under. Without limiting or expanding the foregoing in no event shall (a) the Service Provider be liable for any special, incidental or consequential damages; or (b) the Service Provider's liability for defective Systems exceed the corresponding purchase price of the System.

Service Provider will repair or replace any MedSafe system, at its option, that is deemed defective or in need of repair, subject to the above paragraph for a period of one year from purchase date "Expected Effective Date". This warranty is made on the condition that (i) Participant provides Service Provider with written notice of any defect (in no event later than 30 days from the date of the alleged defect is discovered or should have been discovered, (ii) defective product is inspected by Service Provider and (iii) Service Provider determines that Participant's claim is valid under the terms of this warranty.

Pharmacy Representative

Policy Adoption Date

Pharmacy Name

MEDSAFE POLICY (NON-PHARMACY)

For Participants in the Rx Cares for Missouri program funded by the Missouri Board of Pharmacy ("Participant")



Participant agrees to adopt the following Policy:

- a) Once Participant becomes a DEA-Authorized Collector, Participant agrees to install and manage MedSafe Collection Receptacles in areas regularly monitored by employees, and not in the proximity of any area where emergency or urgent care is provided, in compliance with DEA Regulations on disposal of controlled substances. Disposal of a pharmaceutical controlled substance in Schedules II, III, IV and V into the MedSafe Collection Receptacle may only be performed by ultimate users. Authorized Collectors may only view what ultimate users deposit into the MedSafe Collection Receptacle and they may ask what substances are being deposited. The Participant cannot use the Collection Receptacle to dispose of unused controlled substances in their inventory or stock.
- b) Participant agrees to follow DEA Regulations related to unlocking the Collection Receptacle and removing the MedSafe Inner Liner. The installation, removal, transfer and storage of the MedSafe Inner Liners shall be performed by or under the supervision of two employees of the Authorized Collector.
- c) Participant agrees to replace Inner Liner at the established frequency interval, seal Inner Liner in accordance with included instructions for use and provide to the selected common carrier (UPS) for prepaid return transportation to the treatment facility. Upon removal, sealed Inner Liners will be securely stored at the Authorized Collector's registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer. Participant shall maintain all records as required by DEA regulations.
- d) Participant agrees to display The Missouri Board of Pharmacy and Sharps-approved program signage above the Collection Receptacle.
- e) Participant shall keep confidential any document, information, process, practice, handling method, contract, or agreement provided by Sharps in connection with the MedSafe Program, except whatever is expressly allowed by Sharps.
- f) Participant agrees to only use MedSafe Inner Liners provided by Sharps Compliance, which are designed to work with the MedSafe Collection Receptacle to meet DEA and DOT regulations for collection and disposal of patient and consumer dispensed or expired medications including controlled substances. Pursuant to the Rx Cares for Missouri Program, Participant will be provided twelve (12) inner liners at no cost to the Participant. If further participation in the MedSafe program is desired, the Participant agrees to assume financial responsibility for the purchase of additional four-packs of MedSafe Inner Liners from Sharps Compliance (800) 772-5657 or emailing orders@sharpsinc.com.
- g) Participant agrees to comply with MedSafe Returns and Product Warranty Policy Service Provider warrants that all MedSafe systems are designed to meet all applicable state and federal regulations and are free from defect in material and workmanship when used in accordance with instructions and for their designed purpose for a period of one year from date of purchase. In the event that Participant makes any modifications to the Systems, or if the Participant does not utilize the System in strict accordance with the Instructions for Use (included with the System) or the System is damaged due to the acts or omissions of the Participant or its employees, then the foregoing warranty shall be void and null and Service Provider will have no further liability there under. Without limiting or expanding the foregoing in no event shall (a) the Service Provider be liable for any special, incidental or consequential damages; or (b) the Service Provider's liability for defective Systems exceed the corresponding purchase price of the System.

Service Provider will repair or replace any MedSafe system, at its option, that is deemed defective or in need of repair, subject to the above paragraph for a period of one year from purchase date "Expected Effective Date". This warranty is made on the condition that (i) Participant provides Service Provider with written notice of any defect (in no event later than 30 days from the date of the alleged defect is discovered or should have been discovered, (ii) defective product is inspected by Service Provider and (iii) Service Provider determines that Participant's claim is valid under the terms of this warranty.

Participany Representative

Policy Adoption Date

Participant Name

38-Gallon MedSafe[®]

Properly disposing of unused medications is a vital strategy for aiding in the prevention of prescription drug abuse and keeping the water supply safe. MedSafe is an ultimate-user medication collection and disposal solution. MedSafe generates foot traffic at retail locations, acts as a value-added service for pharmacies managing long-term care facilities, and can be used in hospitals and clinics with on-site pharmacies. A DEA registered collector must manage the program. The MedSafe can also be used in law enforcement and at drug treatment programs.

MedSafe combines a powder-coated, stainless steel collection receptacle with a removable, prepaid shipback inner liner. The receptacle, which secures to the floor or wall, is equipped with two separately keyed locks on the main door and a one-way medicine drop with lock. When the inner liner is full, it is removed from the collection receptacle by authorized persons, securely sealed and returned by way of common carrier for proper destruction.

SYSTEM INCLUDES

- Outbound shipping from seller to customer
- Collection receptacle
- One inner liner, serialized for tracking
- Prepaid return shipping for destruction via common carrier for the inner liner
- Proper destruction and online documentation
- Instructions for use and log for documenting collector steps

ADVANTAGES

- Flexible pricing options available
- Fully compliant with DEA and DOT regulations
- Approved for ultimate-user non-controlled and controlled medications (Schedules II-V)
- Convenient prepaid return shipping for inner liners included
- Online tracking and proof of destruction via SharpsTracer available 24/7
- Drugs destroyed via incineration to meet DEA requirements

