

Emergency Rules

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

EMERGENCY AMENDMENT

19 CSR 30-1.023 Registration Changes. The department is amending sections (1) and (2).

PURPOSE: This amendment allows authorized registrants to modify their registration to allow the collection of unwanted controlled substances.

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

(1) 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, Missouri, 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. 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.

AUTHORITY: section 195.195, RSMo [2000] 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, expires March 25, 2019. An emergency amendment and a proposed amendment covering this same material will be published in the October 15, 2018, issue of the *Missouri Register*.