CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Audits and Investigations
(New Administrative Regulation)

902 KAR 55:120. Disposal of prescription controlled substances.

RELATES TO: 21 C.F.R. Part 1317
STATUTORY AUTHORITY: KRS 218A.250
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 requires the Cabinet for Health and Family Services to promulgate administrative regulations for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes safe, secure, and responsible methods for the disposal of unused or unwanted prescription controlled substances by long-term care facilities and other cabinet-licensed facilities with custodial control of patient-owned controlled substance medications.

Section 1. Methods of Disposal. A long-term care facility or other cabinet-licensed facility with custodial control of patient-owned controlled substance medications shall:

(1) Dispose of all expired, abandoned, or otherwise unwanted controlled substances in accordance with 21 C.F.R. Part 1317; and

(2) Develop and implement written policies and procedures for the disposal of controlled substances. Disposal methods shall include:

(a) On-site destruction that renders the controlled substance unrecoverable and beyond reclamation so that the medication cannot be diverted; or

(b) Transfer of the controlled substance to an authorized collection receptacle maintained by a:

1. Law enforcement agency; or
2. Pharmacy.

Section 2. Procedures for Disposal. (1) If a patient's controlled substance medication has expired, been abandoned, or is otherwise unwanted, either the facility's responsible person or the director of nursing and a witness who is employed by the facility shall perform and document:

(a) Removal of the patient's controlled substances from the medication cart or storage area;

(b) Transfer of the medications to a separate secure storage area; and

(c) Use of a disposal method established by Section 1(2) of this administrative regulation no later than thirty (30) days from the date the patient's controlled substances are removed from the medication cart or storage area.

(2) The facility shall maintain a readily retrievable record of controlled substances removed from the medication cart or other area of storage. The record shall:

(a) Be maintained for a minimum of eighteen (18) months from the date of disposal;

(b) Be made available upon request by the cabinet for purposes of inspection; and

(c) Contain the following information:

1. Amount of controlled substances destroyed on-site or transferred to a collection receptacle;
2. Disposal method;
3. Date of disposal;
4. Patient name;
5. Drug name;

6. Drug strength; and

7. Name of the responsible person or director of nursing and witness responsible for the transfer and disposal of the medications.

(3) Controlled substances shall not be destroyed by flushing into a sewage treatment system unless disposal by flushing is permitted by:

(a) Instructions on the label;

(b) The patient information leaflet with the medication; or

(c) The U.S. Food and Drug Administration's (FDA) flush list posted on the FDA webpage: https://www.fda.gov/media/85219/download.

(4) The cabinet shall take adverse action against a facility's license in accordance with 902 KAR 20:008, Section 8, or 908 KAR 1:370, Section 20, if the cabinet finds that there has been a substantial failure by the facility to comply with the provisions of this administrative regulation.

STEVEN D. DAVIS, Inspector General
ADAM M. MEIER, Secretary

APPROVED BY AGENCY: July 2, 2019

FILED WITH LRC: July 11, 2019 at 2 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on August 26, 2019, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 19, 2019, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until August 31, 2019. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Chase Coffey, Executive Administrative Assistant, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-6746; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Stephanie Brammer-Barnes, email: stephanie.brammer@ky.gov, Phone: 502-564-288; and Chase Coffey

(1) Provide a brief summary of:

(a) What this administrative regulation does: The Cabinet for Health and Family Services, in collaboration with the Office of Drug Control Policy, is promulgating this new administrative regulation to establish safe, secure, and responsible methods for the disposal of unused or unwanted prescription controlled substances by long-term care facilities and other cabinet-licensed facilities with custodial control of patient-owned controlled substance medications.

(b) The necessity of this administrative regulation: In accordance with 21 C.F.R. Part 1317, this administrative regulation is necessary to establish prompt, safe, and effective disposal methods while providing effective controls against the diversion of prescription controlled sub-

stances.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 218A.250 by establishing responsible methods for the disposal of unused or unwanted prescription controlled substances.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing responsible methods for the disposal of unused or unwanted prescription controlled substances.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts long-term care facilities and other cabinet-licensed facilities with custodial control of patient-owned controlled substance medications. There are currently 316 long-term care facilities.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Facilities with custodial control of patient-owned controlled substance medications must dispose of expired, abandoned, or otherwise unwanted controlled substances in accordance with 21 C.F.R. Part 1317. Accordingly, facilities must comply with the two (2) person integrity requirement for disposal, ensure that on-site destruction renders the controlled substance unrecoverable and beyond reclamation so that the medication cannot be diverted, and ensure compliance with recordkeeping requirements. Controlled substances must not be destroyed by flushing into a sewage treatment system unless disposal by flushing is permitted by instructions on the label, the patient information leaflet with the medication, or the U.S. Food and Drug Administration’s flush list. Substantial failure to comply with this administrative regulation shall result in adverse action against a facility’s license.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs will be incurred to comply with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): In an effort to curtail prescription drug abuse, this administrative regulation establishes safe, secure, and responsible methods for the disposal of unused or unwanted controlled substance medications.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of

this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies will be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General. This administrative regulation also impacts long-term care facilities and other cabinet-licensed facilities with custodial control of patient-owned prescription controlled substances.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.250, 21 C.F.R. Part 1317

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any additional revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not general any additional revenue.

(c) How much will it cost to administer this program for the first year? This administrative regulation imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate. 21 C.F.R. Part 1317

(2) State compliance standards. KRS 218A.250

(3) Minimum or uniform standards contained in the federal mandate. 21 C.F.R. Part 1317 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 disposal methods while providing effective controls against the diversion of controlled substances.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.