

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. (46 Ky.R. 824; eff. 11-1-2019.)