

902 KAR 55:070. Emergency medication kits in long-term care facilities.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 218A.010(39), 218A.200(6), 315.335

STATUTORY AUTHORITY: KRS 194A.050(1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Secretary of the Cabinet for Health and Family Service to promulgate administrative regulations necessary to implement programs mandated by federal law, or to qualify for the receipt of federal funds and cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. 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 requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

Section 1. Definitions. (1) "Emergency medication kit" or "EMK" is defined by 201 KAR 2:370, Section 1(3).

(2) "Practitioner" is defined by KRS 218A.010(39).

Section 2. Storage of Controlled Substances in an EMK. (1) A pharmacy provider may place one (1) EMK that contains controlled substances in:

- (a) A residential hospice facility licensed in accordance with 902 KAR 20:380;
- (b) A nursing home licensed in accordance with 902 KAR 20:048;
- (c) A nursing facility licensed in accordance with 902 KAR 20:300;
- (d) An intermediate care facility licensed in accordance with 902 KAR 20:051;
- (e) A personal care home pursuant to 201 KAR 2:370, Section 2(4)(i); or
- (f) An intermediate care facility for individuals with intellectual disabilities licensed in accordance with 902 KAR 20:086.

(2) A long-term care facility with an EMK shall:

(a) Implement and maintain on-site a copy of written policies and procedures developed in consultation with the pharmacy provider, including responsibilities specific to the facility and the pharmacy as it relates to procuring, using, storing, securing, and replacing controlled substances in the kit;

(b) Maintain a complete and accurate record of all controlled substances to be kept in the EMK, including the disposition of the controlled substances; and

(c) Ensure that the EMK is stored in a limited access area such as a securely locked:

- 1. Substantially constructed cabinet; or
- 2. Room with restricted access.

(3) Controlled substances in the EMK shall be the property of the pharmacy provider.

(4) The pharmacy provider shall:

(a) Implement and maintain a copy of the written policies and procedures required by subsection (2)(a) of this section;

(b) Maintain a complete and accurate record of all controlled substances to be kept in the EMK, including the disposition of the controlled substances;

(c) Be responsible for the labeling, storage, security, and accountability of all controlled substances in the EMK;

(d) Document completion of a physical inventory of the controlled substances no less than one (1) time per month; and

(e) Report theft or loss of controlled substances from the EMK pursuant to:

- 1. KRS 218A.200(6);

2. KRS 315.335; and

3. 201 KAR 2:205, Section 2(3)(g).

(5) Controlled substances stored in the EMK shall be selected by the facility's:

(a) Medical director or other physician;

(b) Consultant pharmacist; and

(c) Director of nursing.

(6) Controlled substances in the EMK shall not exceed six (6) individual doses each of ten (10) different controlled substances, plus two (2) multi-dose packages in the smallest unit that is commercially available.

(7) A controlled substance from the EMK shall be administered only upon the prescription order of an authorized practitioner who determines that the resident has an immediate medical need.

(8) Access to a controlled substance in the EMK shall be limited to a:

(a) Practitioner;

(b) Registered nurse; or

(c) Other person authorized by law in this state to access and administer the prescribed medication.

(9) If an EMK is opened for any reason, the facility shall notify the pharmacy provider within twenty-four (24) hours after the kit has been opened for the pharmacy to restock and reseal the kit promptly, if necessary.

Section 3. Adverse Action. (1) The Cabinet for Health and Family Services shall deny, suspend, or revoke the privilege of supplying or possessing an EMK if the cabinet finds substantial noncompliance with Section 2 of this administrative regulation.

(2) The pharmacy provider or facility may file an appeal with the cabinet within (10) calendar days of the cabinet's notice of denial, suspension, or revocation.

(3) If the pharmacy provider or facility requests an administrative hearing, the cabinet shall:

(a) Appoint a hearing officer; and

(b) Proceed pursuant to KRS 13B.050.

(4) The administrative hearing shall be conducted by a hearing officer appointed by the secretary and held in accordance with KRS 13B.080, 13B.090, and 13B.110.

(5) The secretary shall issue a final order in accordance with KRS 13B.120. (15 Ky.R. 1352; eff. 12-13-1988; 20 Ky.R. 2227; eff. 3-14-1994; 22 Ky.R. 2481; eff. 8-1-1996; 33 Ky.R. 2218; 2973; eff. 4-6-2007; Crt eff. 05-07-2019; 46 Ky.R. 270; eff. 11-18-2019.)