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

902 KAR 55:070.[~~Storage of controlled substances in an~~] Emergency medication kits[~~kit~~] in[~~certain~~] long-term care facilities.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 218A.010(39),[~~218A.180,~~] 218A.200(6), 315.335

STATUTORY AUTHORITY: KRS 194A.050(1)[~~194.050~~], 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[~~directs~~] the Cabinet for Health and Family Services to promulgate [~~adopt rules and~~] administrative regulations for carrying out the provisions of KRS Chapter 218A[~~relating to controlled substances~~]. This administrative regulation establishes requirements related to the placement of[~~authorizes the storage in an~~] emergency medication kits with controlled substances[~~kit~~] in [~~certain~~] long-term care facilities[~~of limited quantities of controlled substances to be administered if prescribed by an authorized practitioner~~].

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

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

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

(a) A[~~store controlled substances in an emergency medication kit in 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[~~, skilled nursing facility,~~] 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[~~the mentally retarded if the following conditions are met: (1)~~] 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)[~~of the facility regarding the procurement, use, storage, security, replacement, and recordkeeping of controlled substances in the kit shall be filed with the facility and with the pro-~~

~~vider pharmacy; (2)~~] Controlled substances in the EMK[~~kit~~] shall be the property of the[~~provider~~] 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[~~, which is~~] responsible for the[~~their proper~~] 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)[~~; (3)~~] Controlled substances stored in the EMK[~~kit~~] shall be selected[~~jointly~~] by the facility's:

(a) Medical director or other physician;

(b)[~~,~~] Consultant pharmacist; [~~,~~] and

(c)[~~The~~] Director of nursing.

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

(7) A[~~; (5)~~] controlled substance from[~~substances in~~] the EMK [~~kit~~] shall be administered only upon the prescription[~~the~~] order of an authorized practitioner who determines that the resident[~~patient~~] has an immediate medical need.

(8)[~~; (6)~~] Access to a[~~the~~] controlled substance[~~substances~~] in the EMK[~~kit~~] shall be limited to a:

(a) Practitioner;

(b)[~~physician, pharmacist,~~] 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,[~~; (7)~~] the facility shall notify the pharmacy provider[~~pharmacy shall be notified by the facility~~] within twenty-four (24) hours after the kit has been opened for the pharmacy to restock and reseal the kit promptly, if necessary. [~~;(8) The prescribing practitioner shall issue a written prescription for the controlled substances to the provider pharmacy within seventy-two (72) hours after administration of a controlled substance from the kit;~~

~~(9) The facility shall maintain a record of the administration of controlled substances from the kit in accordance with applicable state and federal laws;~~

~~(10) The provider pharmacy shall document documents a physical inventory of the controlled substances in the kit at least monthly; and~~

~~(11) The loss of any controlled substance from the kit shall be reported to the Cabinet for Health and Family Services in accordance with KRS 218A.200(6) and to the Federal Drug Enforcement Administration in accordance with 21 C.F.R. 1301.74(c).~~]

Section 3. Adverse Action. (1)[~~2.~~] The Cabinet for Health and Family Services shall[~~may~~] deny, suspend, or revoke the privilege of supplying or possessing an EMK if the cabinet finds substantial noncompliance with[~~storing controlled substances in an emergency medication kit if~~

~~any provision in~~] Section 2[~~1~~] of this administrative regulation[~~is violated~~].

(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[~~All administrative hearings shall be conducted in accordance with 902 KAR 1:400~~].

(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.

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

APPROVED BY AGENCY: May 21, 2019

FILED WITH LRC: June 13, 2019 at noon

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on July 22, 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 July 15, 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 July 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; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Stephanie Brammer-Barnes and Chase Coffey

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 218A.250, which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for carrying out the provisions of KRS Chapter 218A. Additionally, the Drug Enforcement Administration (DEA) issued a policy statement that provides individual state licensing and regulatory agencies with general guidelines for establishing specific rules concerning controlled substances used in emergency kits in long-term care facilities, see Pharmacist's Manual – Appendix H, *Guidelines for Emergency Kits in Long Term Care Facilities:* https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/appendix/appdx_h.htm. Appendix H

states that "a pharmacy may place an emergency kit with controlled substances in a non-DEA registered Long Term Care Facility (LTCF), if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate" the source from which a facility may obtain controlled substances for an emergency kit, security safeguards, and other requirements for the proper use and storage of an emergency kit.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 218A.250 and Pharmacist's Manual – Appendix H by establishing requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

(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 requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

(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 amendment changes the existing administrative regulation as follows:

Replaces the previous title with a new title, "Emergency medication kits in long-term care facilities;

Defines the terms "emergency medication kit (EMK)" and "practitioner";

Clarifies that no more than one (1) EMK may be placed in an LTCF, including a personal care home that meets the requirements of 201 KAR 2:370, Section 2(4)(i);

Clarifies that both the LTCF and pharmacy provider shall maintain a complete and accurate record of all controlled substances to be kept in the EMK, including the disposition of the controlled substances as required by the DEA Pharmacist's Manual – H, A.3.;

Increases the number of controlled substances that may be stored in an EMK from six (6) individual doses each of six (6) different controlled substances to six (6) individual doses each of ten (10) different controlled substances, and also allows for the storage of two (2) multi-dose packages in the smallest unit that is commercially available;

Updates the cross-references to state laws and administrative regulations that require a pharmacy provider to report theft of loss of a controlled substance from the EMK;

Requires the cabinet to deny, suspend, or revoke the privilege of supplying or possessing an EMK if the cabinet finds substantial noncompliance with the requirements of this administrative regulation; and

Makes technical changes for compliance with KRS Chapter 13A to improve clarity and flow.

(b) The necessity of the amendment to this administrative regulation: This amendment has been filed upon consideration of a request from the Kentucky Association of Health Care Facilities to modify the limit on the quantity of controlled substances currently allowed to be stored in an EMK. Therefore, the cabinet has agreed to increase the number of controlled substances that may be stored in an EMK from six (6) individual doses each of six (6) different controlled substances to six (6) individual doses each of ten (10) different controlled substances, and allow for the storage of two (2) multi-dose packages in the smallest unit that is commercially available for a total of twelve (12) different controlled substances in the EMK. Although states' rules and regulations on this issue vary, including some states without a defined limit on the number of controlled substances or doses placed in an EMK, the Cabinet's proposal maintains a defined limit to help reduce the potential for diversion, yet provides for a reasonable increase in the limit to address issues related to emergency access to controlled substances needed for immediate administration.

(c) How the amendment conforms to the content of the authorizing statutes: This amend-

ment conforms to the content of KRS 218A.250 and the DEA Pharmacist's Manual – Appendix H by establishing requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by establishing requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation impacts pharmacy providers that place an EMK in a long-term care facility as well as facilities that administer controlled substances from an EMK.

(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: To comply with this amendment, a long-term care facility with an EMK shall implement and maintain on-site written policies and procedures developed in consultation with the pharmacy provider, including responsibilities specific to procuring, using, storing, securing, and replacing controlled substance in the kit; maintain a complete and accurate record of all controlled substances to be kept in the EMK; and ensure that the EMK is stored in a limited access area. The pharmacy provider shall be responsible for maintaining policies and procedures developed in consultation with the long-term care facility; maintain a complete and accurate record of all controlled substances to be kept in the EMK; assume responsibility for the labeling, storage, security, and accountability of all controlled substances in the EMK; document completion of a physical inventory of the controlled substances no less than one (1) time per month; and report theft or loss of controlled substances from the EMK in accordance with applicable state laws and administrative regulations. In addition, controlled substances stored in the EMK shall be selected by the facility's medical director or physician, consultant pharmacist, and director of nursing. Controlled substances stored in the EMK shall not exceed the limit established by Section 2(6) of this administrative regulation. Further, this administrative regulation establishes requirements related to administration of controlled substances from the EMK, access to medications in the EMK, and notification to the pharmacy provider if an EMK is opened for any reason.

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

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment increases the number of controlled substances that may be stored in an EMK from six (6) individual doses each of six (6) different controlled substances to six (6) individual doses each of ten (10) different controlled substances, and also allows for the storage of two (2) multi-dose packages in the smallest unit that is commercially available for a total of twelve (12) different controlled substances in the EMK. This change will allow for urgent doses of needed medications to be administered immediately to residents who are in need.

(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 related to implementation of this amendment.

(b) On a continuing basis: There are no additional costs to the cabinet related to implementation of this amendment 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 are 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 amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This amendment 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 pharmacy providers and long-term care facilities 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, and pharmacy providers that place an EMK in a long-term care facility as well as facilities that administer controlled substances from an EMK.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050, 218A.250

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 amendment 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 amendment will not general any additional revenue.

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

(d) How much will it cost to administer this program for subsequent years? This amendment 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: