BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:370. Pharmacy services in long-term care facility (LTCF).

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: KRS 315.002, 315.005, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and require the board to ensure safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in long-term care facilities.

Section 1. Definitions.

(1) "Automated Dispensing System" or "ADS" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

(2) "Emergency Drug" means drugs required to meet the immediate therapeutic needs of patients that are not available from any other authorized source in sufficient time to prevent risk of harm to patients because of delay.

(3) "Emergency Medication Kit" or "EMK" means an onsite manual or automated mechanism for delivering emergency medications.

(4) "Immediate supervision" is defined by KRS 315.010(12).

(5) "Individual dose" means smallest unit that is commercially available.

(6) "Long-term care facility" or "LTCF" is defined by KRS 216.510(1), excluding family-care homes and assisted living communities.

(7) "Long Term Care Facility Drug Stock" or "LTCF drug stock" means a dose or doses generated from a prescription order sufficient until the next pharmacy business day or IV fluids that are used for replenishment, which contain no additive drugs, or irrigation solutions.

(8) "Pharmacist-in-charge" or "PIC" means a pharmacist mandated as in charge under KRS 315.020 and who meets the requirements of 201 KAR 2:205.

(9) "Supervision" is defined by KRS 315.010(27).

(10) "Tamper-resistant secure container" means an enclosed container used in a tamper-resistant ADS and designed to prevent the opening of the container and manipulation of medications prior to loading the ADS and after the contents of the container have been enclosed and verified by a pharmacist.

Section 2. General Requirements.

(1) The pharmacist-in-charge of the dispensing pharmacy shall:

(a) Be responsible for policies and procedures governing the procurement, distribution, storage, security, access, administration, and control of all drugs that are provided to a LTCF;

(b) Review all policies and procedures at least once every twelve (12) months;

(c) Provide LTCF drug stock or an EMK only to facilities that authorize entry by a board agent for the purposes of inspection or investigation of the LTCF drug stock or EMK at the facility;

(d)

1. Maintain written authorization for entry; and

2. Immediately provide written authorization for entry to the board upon request of a board agent; and

(e) Maintain a current list of all locations where LTCF drug stock or an EMK are stored, which shall be made immediately available upon request by a board agent.

(2) Dispensing.

(a) Controlled substance medications shall be dispensed only by prescription drug order of a licensed practitioner.

(b) Non-controlled substance medications shall be dispensed only on a medical order or prescription drug order of a licensed practitioner.

(c) A medical order entered on the medical record of a patient at a LTCF shall contain:

1. Name of patient;
2. Date of issuance;
3. Name, strength, and dosage form of drug prescribed;
4. Directions for use; and
5. Practitioner's name.

(d) Each licensee shall comply with United States Pharmacopeia (USP) Chapter 7 Labeling regarding labeling and packaging.

(3) The services of a pharmacist shall be readily available at all times.

(4) Emergency drugs.

(a) Emergency drugs for controlled substances in a LTCF EMK shall be stocked pursuant to 902 KAR 55:070.

(b) Emergency drugs for non-controlled substances in an EMK shall not exceed six (6) individual doses of thirty (30) different non-controlled substances, per LTCF.

(c) The pharmacist-in-charge may request a waiver from the board to increase the number of doses or numbers of non-controlled substances in the EMK based on evidence of use.

(d) An EMK shall be assessed for outdated, damaged or adulterated drugs, and stock adequacy by:

1. A pharmacist or any lawful person as stated in 902 KAR 55:070 on a monthly basis for controlled substances; or
2. A pharmacist, a PIC authorized pharmacist intern, or certified pharmacy technician on a monthly basis for non-controlled substances.

(e) EMK drugs shall be supplied in unit dose packaging unless precluded by manufacturer packaging.

(f) An EMK shall be conspicuously labeled.

(g) An EMK drug shall be accessed only upon a lawful prescription order.

(h) All prescription orders shall be reviewed by a pharmacist within one (1) pharmacy business day.

(i) An EMK shall not be stocked in a personal care home without personnel lawfully licensed to administer medications.

(5) Initial dose of LTCF drug stock in a LTCF.

(a) Excluding personal care homes, LTCF drug stock of drugs shall not exceed fifteen (15) individual doses each of 150 non-controlled substances.

(b) LTCF drug stock in a personal care home shall not exceed five (5) individual doses each of thirty (30) non-controlled substances.

(c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be placed in LTCF drug stock based upon evidence of use.

(d) The pharmacist-in-charge shall be responsible for authenticating the need for LTCF drug stock.

(e) A pharmacist shall review the prescription drug or medical order before the release of medication.

(f) LTCF drug stock shall be inspected by pharmacy personnel at least monthly and documentation shall be maintained to determine if:

1. Medications are outdated; and
2. Stocks are maintained at adequate levels.

(g) Except for LTCF drug stock of intravenous fluids with no additive drugs or irrigation solutions, the LTCF drug stock shall be replenished by:

1. A tamper-resistant secure container delivered from the pharmacy;
2. A tamper-resistant secure container for the stocking of an ADS;
3. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the immediate supervision of a pharmacist on-site, if there is no pharmacy on-site; or
4. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the supervision of a pharmacist, if there is a pharmacy on-site.

Section 3. The pharmacist-in-charge of an ADS in a LTCF shall be responsible for the following:

(1) Initial validation of the ADS accuracy prior to use for distribution to patients assuring that the ADS:

(a) Is in good order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

(b) Complies with the recordkeeping and security safeguards pursuant to Section 4 of this administrative regulation.

(2) Assuring that non-controlled substance prescription drug orders and medical orders are reviewed and approved by a pharmacist prior to access, except for emergency drugs;

(3) Assuring that controlled substance prescription drug orders are reviewed and approved by a pharmacist prior to accessing the controlled substance emergency drugs;

(4) Implementing an ongoing quality assurance program that monitors performance of the ADS, pursuant to the written policies and procedures;

(5) Assigning, discontinuing, or changing personnel access to the system; and

(6) Assuring appropriate access to medications.

Section 4. Standards. A permit holder utilizing an ADS shall comply with the following provisions:

(1) A pharmacy shall maintain the following documentation:

(a) Name and address of the LTCF where the system is being used;

(b) The ADS manufacturer's name, model, and serial number;

(c) An operations manual;

(d) Description of how the system is used;

(e) Written quality assurance procedures to determine continued appropriate use of the system; and

(f) Written policies and procedures for system operation, safety, security, accuracy, access, and malfunction.

(2) All written policies and procedures shall be maintained in the pharmacy responsible for the ADS.

(3) An ADS shall maintain adequate security systems and procedures, pursuant to written policies and procedures that prevent unauthorized access to patient records and maintain patient confidentiality.

(4) ADS records and data shall meet the following requirements:

(a) All events involving the contents of the ADS shall be recorded electronically; and

(b) Records shall be maintained by the pharmacy for five (5) years, be available to the board, and shall include the following:

1. The time and location of each system access;
2. Identification of the individual accessing the system;

3. Name of the patient for whom the drug was ordered;
4. Name, strength, dosage form, and quantity of drug accessed;
5. Type of transaction;
6. The prescription or transaction number if assigned; and
7. The name of the prescriber.

(c) All events involving user database modifications shall be recorded electronically and maintained.

(d) A twenty-four (24) hour emergency call center shall be available for any ADS malfunction.

(5) The stocking of all medications in an ADS shall be performed by a:

(a) Pharmacist;

(b) Pharmacist intern; or

(c) Certified pharmacy technician who shall be under the supervision of a pharmacist on-site.

(6) If the pharmacy utilizes a tamper resistant barcoding technology, microchip, or other equivalent tamper-resistant ADS, a pharmacist-verified drug may then be loaded by a pharmacist-in-charge trained pharmacist, pharmacist intern, or certified pharmacy technician.

(7) A record of medications stocked in an ADS shall be maintained for five (5) years and shall include identification of the person stocking the ADS and the pharmacist checking for accuracy.

(8) The pharmacist-in-charge shall provide a policy for accounting for medications removed from an ADS and subsequently wasted.

(9) The pharmacist-in-charge shall provide a policy for accounting for medications returned to an ADS.

Section 5. Incorporation by Reference.

(1) "USP Chapter 7 Labeling", (September 1, 2023)[(December 1, 2017)], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m. or on the board's Web site at https://pharmacy.ky.gov/statutesandregulations/Pages/default.aspx.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: June 4, 2024

FILED WITH LRC: June 4, 2024 at 11:15 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 28, 2024, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five 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 wishes to be heard 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 the proposed administrative regulation. Written comments shall be accepted through August 31, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.Harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation regulates pharmacy services in long-term care facilities.

(b) The necessity of this administrative regulation:
KRS 315.191 requires the board to regulate and control all matters set forth relating to pharmacists, pharmacies and the dispensing of drugs.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This regulation establishes rules for pharmacy services, as authorized in KRS 315.191(1)(a).

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
Pharmacists and pharmacies will have a clear understanding of what is authorized and what is not authorized regarding pharmacy services 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:
The amendment ensures that the automated dispensing systems utilized in long-term care facilities are loaded in a tamper-proof manner where drugs cannot be diverted by technicians loading the systems.

(b) The necessity of the amendment to this administrative regulation:
To ensure that the risk of drug diversion is mitigated.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 315.191(1)(a) authorizes the board to regulate all matters relating to pharmacists and pharmacies. Pharmacies service long-term care facilities ensuring drug stocks are maintained for dispensing.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment will ensure pharmacists and technician duties are clearly articulated and that automated dispensing systems are loaded in such a way that diversion is not a possibility.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
Pharmacies serving long-term care facilities, pharmacists and technicians.

(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:
Pharmacists and pharmacies that serve long-term care facilities will need to ensure that they familiarize themselves with the new rule regarding tamper-resistant containers for automated dispensing systems.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

There are no expected costs for those identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

There will be a reduced risk of diversion and tampering with prescription drugs. (5) Provide an estimate of how much it will cost to implement this administrative regulation:

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

(a) Initially:

No costs will be incurred.

(b) On a continuing basis:

No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Board revenues from pre-existing fees provide the funding to enforce the 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 will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies equally.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.
KRS 315.191(1)(a).

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
There will be no expenditures or cost savings.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):
None, only the Kentucky Board of Pharmacy is impacted.

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
This regulation does not create any expenditures, revenues or cost savings.

(4) Identify additional regulated entities not listed in questions (2) or (3):
none.

(a) Estimate the following for the first year:

Expenditures:none.

Revenues:none.

Cost Savings:none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
This regulation does not create any expenditures, revenues or cost savings.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
There is no fiscal impact from this regulation.

(b) Methodology and resources used to determine the fiscal impact:
There are no fees or costs associated with this regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)

This administrative regulation will not have an overall negative or adverse major economic impact to the entities identified.

(b) The methodology and resources used to reach this conclusion:

There are no costs, expenditures or revenues from this regulation.