BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:260. Automated Pharmacy System in residential hospice facilities.

RELATES TO: KRS 216B.195, 315.010(9), 315.020, 315.035, 315.295, 315.300

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 335.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.295 authorizes the board to regulate an automated pharmacy system in a residential hospice facility. This administrative regulation establishes the standards for the operation of this type of system.

Section 1. Definitions.

(1) "Automated Pharmacy System" is defined by KRS 315.295(1)(a).

(2) "Residential Hospice Facility" is defined by KRS 315.295(1)(b).

Section 2. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for all of the following:

(1) Assuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed and complying with the recordkeeping and security safeguards pursuant to Section 3 of this administrative regulation;

(2) Assuring medications are reviewed by a pharmacist prior to access;

(3) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures; and

(4) Notifying the board with prior written notice of the installation or removal of an automated pharmacy system. This notification shall include the following:

(a) Name and address of pharmacy;

(b) Initial location of the automated pharmacy system. The automated pharmacy system may thereafter be relocated within the pharmacy or health care facility without providing subsequent notification to the board; and

(c) Pharmacist-in-charge.

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

(6) Assuring that access to the medications comply with state and federal laws; and

(7) Assuring that the automated pharmacy system is stocked accurately and that the automated pharmacy system stock is checked monthly in accordance with established written policies and procedures, including the following:

(a) Accuracy;

(b) Integrity; and

(c) Expiration date.

Section 3. Standards. An automated pharmacy system shall comply with the following provisions:

(1) A pharmacy shall maintain on-site the following documentation relating to an automated pharmacy system:

(a) Name and address of the pharmacy or inpatient health care facility where the system is being used;

(b) The automated pharmacy system manufacturer's name, model, and serial number;

(c) Description of how the system is used;

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

(e) 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 automated pharmacy system.

(3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(4) Records and data kept by the automated pharmacy system shall meet the following requirements:

(a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and

(b) Records shall be maintained by the pharmacy and be available to the Board and shall include the following:

1. The time and location of the system accessed;
2. Identification of the individual accessing the system;
3. Type of transaction;
4. Name, strength, dosage form and quantity of drug accessed;
5. Name of the patient for whom the drug was ordered;
6. The prescription number;
7. The name of the prescriber; and
8. All events involving user database modifications shall be recorded electronically and maintained.

(5) The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, pharmacist intern, or pharmacy technician pursuant to 201 KAR 2:045.[~~, who shall be under the general supervision of a pharmacist on-site.~~]

(6) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) The automated pharmacy system shall provide a mechanism for securing and accounting for medications returned to the system and accounting for wasted medications in accordance with federal and state laws.

CHRISTOPHER HARLOW, PharmD, Executive Director

APPROVED BY AGENCY: December 4, 2025

FILED WITH LRC: December 12, 2025 at 10:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 27, 2026, at 9:00 a.m. EST via a 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 was received by that date, the hearing may be cancelled. 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 February 28, 2026. 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

Subject Headings:Pharmacy; Drugs and Medicines; Health and Medical Services

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This regulation governs the use of automated pharmacy systems in residential hospice facilities, establishing standards for their installation, operation, security, quality assurance, record-keeping and pharmacist oversight.

(b) The necessity of this administrative regulation:
The regulation is necessary to ensure the safe and compliant operation of automated pharmacy systems in residential hospice facilities by establishing standards for security, accountability, pharmacist oversight, and drug integrity. It provides the framework needed for the Board to regulate these systems in a way that protects patients, ensures proper handling of medications, and aligns with the Board's statutory duty to oversee the practice of pharmacy in all settings.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
KRS 315.191 requires the Board to protect the public and ensure the safe practice of pharmacy, including oversight of how drugs are stored, accessed, and dispensed. This regulation fulfills that mandate by establishing the operational, security, and oversight framework for automated pharmacy systems in hospice settings. KRS 315.295 requires the Board develop regulations to govern automated pharmacy systems in residential hospice facilities.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
The regulation assists in administering the statutes by providing clear, enforceable standards for the operation and oversight of automated pharmacy systems, enabling the Board to consistently monitor compliance, ensure drug security, and protect patients as required by KRS 315.191.

(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 clarifies the role that a pharmacy technician can play with regards to stocking of an automated pharmacy system in accordance with 201 KAR 2:045.

(b) The necessity of the amendment to this administrative regulation:
This amendment is necessary because it clarifies that a pharmacy technician can only stock an automated pharmacy system in a hospice setting if a pharmacist is on-site pursuant to 201 KAR 2:045.

(c) How the amendment conforms to the content of the authorizing statutes:
The amendment clarifies the role that a pharmacy technician can play with regards to stocking of an automated pharmacy system in accordance with 201 KAR 2:045.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment assists in administering the statutes by providing clear, enforceable standards for the operation and oversight of automated pharmacy systems including the role that a pharmacy technician may play in a residential hospice setting.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No. KRS 315.295 (2006).

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The board anticipates no one will be affected by the administrative regulation amendment as the same protections are already enacted by other provisions of Kentucky law.

(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment:

Pharmacies, pharmacists and pharmacy technicians will have to familiarize themselves with new amended language in the regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

Compliance with the regulation ensures safe and secure medication handling in hospice settings, reducing risks to patients and improving the accuracy and accountability of automated pharmacy systems. It also provides pharmacies with clear operational standards, supports consistent Board oversight, and helps prevent regulatory or disciplinary issues. (6) Provide an estimate of how much it will cost to implement this administrative regulation:

(6) 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.

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

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(8) 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.

(9) 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.

(10) TIERING: Is tiering applied?

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

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, KRS 315.295

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:

No. KRS 315.295 requires the Board develop regulations to govern automated pharmacy systems in residential hospice facilities.

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):

Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:{Response}

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):

None.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

(b) Methodology and resources used to reach this conclusion:

None.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):

No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

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

Analysis of the Board’s expenditures as well as an assessment regarding cost of compliance for regulated entities.