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.

(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.

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